

Viral Hepatitis NBS User Guide

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<u>References</u>

CDC: The ABCs of Hepatitis

http://www.cdc.gov/hepatitis/Resources/Professionals/PDFs/ABCTable.pdf

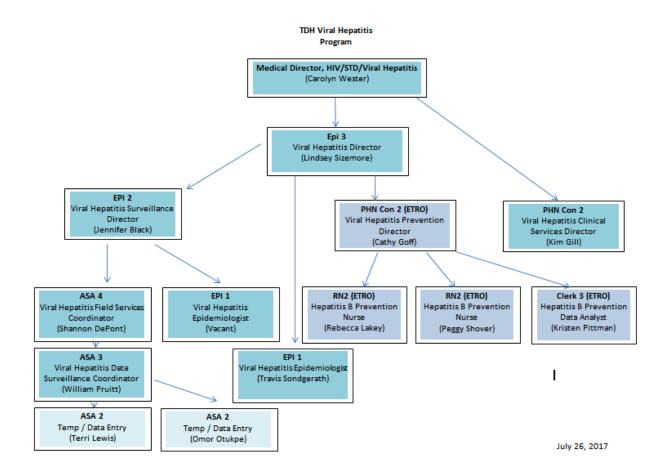
CDC: Interpretation of Hepatitis B Serologic Test Results http://www.cdc.gov/hepatitis/hbv/pdfs/serologicchartv8.pdf

Hepatitis B Foundation: Additional Blood Tests

http://www.hepb.org/patients/additional_blood_tests.htm

Viral Hepatitis Program

Organizational Chart



Monthly Calls

The Viral Hepatitis Monthly Calls occur the 4^{th} Thursday of every month from 8:00-9:00CST/9:00-10:00EST.

The Viral Hepatitis Case Navigator Calls immediately follow.

Important Terminology: Viral Hepatitis

Hepatitis B Virus (HBV): A double-stranded deoxyribonucleic acid (DNA) virus in the family Hepadnaviridae and genus *Orthohepadnavirus*. It is most commonly transmitted by sexual contact but can also be transmitted by contact with other body fluids. It is vaccine preventable.

Hepatitis C Virus (HCV): An enveloped, single-stranded ribonucleic acid (RNA) virus in the family Flaviviridae and genus *Hepacivirus*. It is a blood-borne pathogen and is not vaccine preventable.

Vertical Transmission (Perinatal Transmission): A pathogen transmitted from mother to baby in pregnancy or during childbirth.

Immunoglobulin M (IgM): The first antibody (Ab) particle produced by the immune system in response to an antigen (infection). Presence of IgM antibodies can signify a recently acquired infection.

Immunoglobulin G (IgG): An antibody (Ab) particle produced by the immune system in response to an antigen (infection). Presence of IgG antibodies can signify a past or present infection.

IgM antibody to hepatitis B core antigen (IgM anti-HBc): Positivity indicates recent infection with hepatitis B virus (≤6 months).

Hepatitis B Surface antigen (HBsAg): A protein on the surface of hepatitis B virus; it can be detected in high levels in serum during acute or chronic hepatitis B virus infection. The presence of HBsAg indicates that the person is infectious.

Hepatitis B e-antigen (HBeAg): A protein that is secreted by hepatitis B infected cells. It is associated with chronic hepatitis B infection and is used as a marker of active viral disease and a patient's degree of infectiousness.

Hepatitis B Surface antibody (anti-HBs): The presence of anti-HBs is generally interpreted as indicating recovery and immunity from hepatitis B virus infection, either naturally or through vaccination.

Total Hepatitis B core antibody (anti-HBc): The total anti-HBc appears at the onset of symptoms in acute hepatitis B and persists for life. It indicates previous or ongoing infection with hepatitis B virus in an undefined time frame.

Hepatitis B e antibody (anti-HBe): An antibody made in response to the B e-antigen and is detected in patients who have recovered from hepatitis B infection as well as those who are chronically infected. **Hepatitis C antibody (anti-HCV):** The presence of antibodies to hepatitis C virus in the blood. It indicates previous or ongoing infection with hepatitis C virus.

Nucleic Acid Test (NAT)/Nucleic Acid Amplification Test (NAAT): A molecular technique that tests for the presence of a virus or bacterium by testing for the presence of viral DNA (for HBV)/viral RNA (for HCV). NAT testing can be quantitative or qualitative and includes polymerase chain reaction (PCR) and genotype tests. For example, in an NBS Hepatitis C investigation, if you receive a positive result for an RNA, PCR, or genotype test, you will mark 'positive' for HCV RNA result.

Window Period: The period of time after a person is infected with a communicable disease but before antibodies to the infection is detectable on testing. During the window period, a patient's antibody test will be negative despite the fact that the patient is infected.

Acute Viral Hepatitis: The early stage of viral infection of the liver caused by one of three different hepatitis viruses (A, B, or C). Signs and symptoms of early (or acute) viral hepatitis include yellowing of the skin or eyes (jaundice), abdominal pain, vomiting, nausea, diarrhea, malaise, grey-colored stools, or dark urine. For Hepatitis B and C, acute infection can lead to chronic infection.

Chronic Viral Hepatitis: A long-term illness that occurs when Hepatitis B or Hepatitis C remains in a person's body. Chronic hepatitis can last a lifetime and lead to serious liver problems, including cirrhosis (scarring of the liver) or liver cancer.

Sustained Virologic Response (SVR): With successful HCV treatment, the virus will become undetectable in the blood. Patients are considered cured of HCV when the virus remains undetectable in their blood for 12 weeks after the completion of their treatment, which is also known as a sustained virologic response.

Important Terminology: NBS

National Electronic Disease Surveillance System (NEDSS) Based System (NBS): a database that facilitates electronically transferring public health surveillance data to and from public health departments and CDC.

Event: A laboratory report (either paper or electronic) within NBS.

Condition: The disease (hepatitis C, acute; hepatitis C, chronic; hepatitis B, acute; hepatitis B, pregnancy).

Case Status: The classification of the condition utilizing the CDC/CSTE hepatitis case definitions (confirmed, probable, not a case). Case status may evolve as new labs are received and should be updated, regardless of when the investigation was opened.

- Example: an existing HCV chronic, probable investigation from 2010 receives a positive RNA lab in 2016.
 - Associate the recently received lab with the existing investigation.
 - Update case status from 'probable' to 'confirmed'

NBS Investigation: Created within NBS to house information related to a condition.

Investigation Start Date: The date the investigation was opened. The investigation start date will always remain static.

- For example: you receive a positive HBsAg on a patient and you notice they have an existing positive HBsAg lab in NBS from 9/30/2011 and no investigation was created.
 - o Open an investigation and investigation start date will auto-populate to today's date.
 - o Associate both the new and old labs to this investigation.
 - The investigation start date, MMWR week, and MMWR year should not be modified to reflect the earlier lab.
 - If an investigation had been created previously, you would associate the new lab to the
 existing investigation and <u>not</u> modify the existing investigation start date, MMWR week,
 or MMWR year to reflect today's date.

Association: The process of linking all relevant events to investigations within NBS.

Field Investigation: An investigation conducted by regional staff to determine if a viral hepatitis infection is acute and/or if a woman of reproductive age is pregnant. This includes requesting records from a provider and/or interviewing the patient to fill out the case report form. Information obtained from a field investigation must be entered into the NBS investigation.

Reportable: The conditions that are required to be reported to the state health department.

Notifiable: The conditions that require CDC notification.

Woman of Reproductive Age: Any woman aged 11-50.

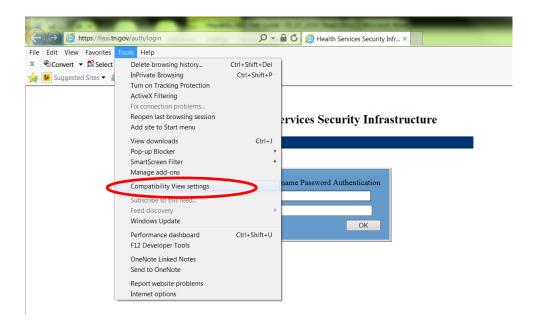
Orphan Laboratory Report: A laboratory report received via Electronic Laboratory Reporting (ELR) that is not associated with an investigation in NBS.

Lab Object: A laboratory report (either paper or electronic) entered within NBS. If verbal laboratory results are given, please make every effort (via lab or provider) to obtain a paper copy of these results and enter them into NBS (so they will count as a lab object). Case status should only be determined from lab objects and not from verbal results.

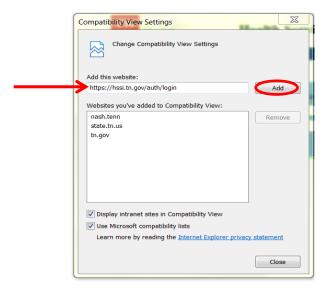
Internet Explorer Configurations for NBS

You will need to modify your Internet Explorer (IE) browser settings to work properly with NBS. Do NOT use any other browser other than IE when using NBS.

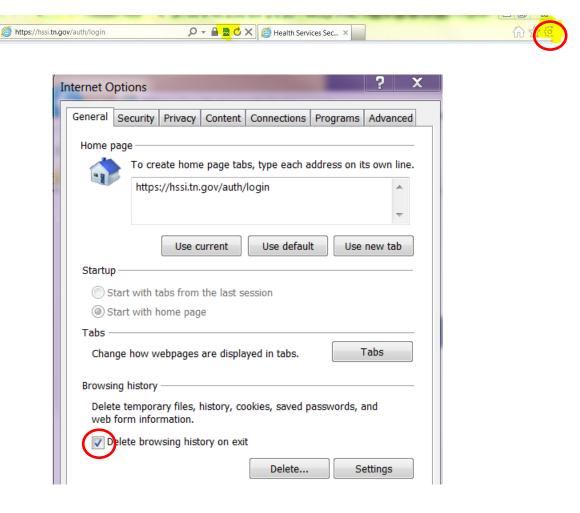
- Link to NBS: https://hssi.tn.gov/auth/login
- Internet Explorer Settings Required for NBS:
 - o Click on Tools, Compatibility View settings



Add web address: https://hssi.tn.gov/auth/login



o Click on the Gear, Go to Internet Options, and check Delete Browsing History on Exit



 If you have tried the incorrect password too many times, and the account has been locked, either wait 45 minutes for the account to unlock automatically or email CEDS.Informatics@tn.gov for assistance.

Please include your DC# and use 'NBS Password Reset' for the Subject of the email. The Surveillance Systems and Informatics Program will contact the Help Desk and the NBS System Administrator to process the request.

Entering Viral Hepatitis Investigations into NBS

This document contains examples of best practices related to management of acute and chronic viral hepatitis (VH) events and investigations In Tennessee, acute HBV, acute HCV, and chronic HCV are reportable; acute HBV and acute HCV are laboratory and provider reportable while chronic HCV is only laboratory reportable.

Tennessee Provider Reportable Diseases, 2017:

https://apps.health.tn.gov/ReportableDiseases/Common/2017 List For Healthcare Providers.pdf

Tennessee Laboratory Reportable Diseases, 2017:

https://apps.health.tn.gov/ReportableDiseases/Common/2017_List_For_Laboratories.pdf

All laboratories should be reporting to the Tennessee Department of Health; however, if a region finds a provider where laboratory reports are not being received consistently, please let Central Office VH staff know. Although laboratories are required to report positive viral hepatitis markers, they have no way to distinguish acute versus chronic infection. Additionally, laboratories are required to report negative hepatitis markers if one or more markers are positive (e.g. if the hepatitis B surface antigen result is positive, labs should report all tests performed for hepatitis A, hepatitis B, and hepatitis C). When lab reports are received, an NBS investigation should be created and any related lab reports (paper or ELR) should be associated with the investigation. This applies to positive and negative labs.

Example: An acute HBV case is reported with a positive HBsAg, a negative anti-HCV, and a negative HAV IgM. All three should be entered and associated with the acute HBV investigation. In this scenario, there should be no additional investigations created in NBS for HAV or HCV.

Although chronic HBV and HCV cases are not provider reportable in Tennessee, NBS serves as a registry for chronic hepatitis cases. All chronic HBV cases will be handled through the region that corresponds to the patient address information listed on the laboratory report. All chronic HCV cases will be handled through the central office and field staff will only be notified if a case is suspected to be acute. The region will be notified by a direct email from central office staff on a case by case basis.

All clinician reported cases of acute hepatitis must have a field investigation and an NBS investigation to determine if the case is acute hepatitis, chronic HCV hepatitis, or not a case. The Centers for Disease Control and Prevention (CDC)/Council of State and Territorial Epidemiologists (CSTE) HBV and HCV case definitions, HBV and HCV case classification boxes, and specific applications of case status can be found in Appendix A. Case status should only be determined from laboratory reports (lab objects) that have been entered (either manually or by ELR) into NBS and associated with an investigation.

Additionally, it is critically important to make every attempt to interview acute HBV and HCV cases diagnosed in jail or prison. It is best practice to call the medical staff at the facility to discuss the case with the nurse in charge and to set up a time to go and interview the patient.

The case report form, a letter requesting records from a provider, a letter requesting records from a provider pertaining only to HBV positive females of reproductive age (11-50), a letter of public health authority, a PH-1600 form, a letter for contacts to an acute HBV or HCV case, and the Accurint Record Search Request Form can be found in Appendix B. In an effort to develop and sustain streamlined statewide tools, <u>only</u> use these resources and contact central office surveillance staff should a problem arise. Additionally, these documents are available in Word on SharePoint at:

https://tennessee.sharepoint.com/sites/health/CEDEP/HSVH/Documents/Forms/Default.aspx?id=%2Fsites%2Fhealth%2FCEDEP%2FHSVH%2FDocuments%2FViral%20Hepatitis%2FVH%20Surveillance

To request a new NBS user, please go to the survey at this address: https://is.gd/NBSUserRequest

- a) Complete the form to request the user access level and program areas.
- b) Please ensure the two IT forms (20170111_ComputerAccessSecurityForm.pdf, 20170111_AcceptableUseForm.pdf) are attached. They may be downloaded, completed, and uploaded in the survey. The account cannot be set up without these two forms attached.
 - a. Choose 'General Communicable Disease' option for domains.
- c) The new user will receive an email with the account instructions and the NBS user guide.

For instructions on adding a provider, instructions on adding an organization (laboratory or medical facility), and the lab translator sheet for to assist with adding a laboratory report, refer to Appendix C. For detailed guidance on the Case Notifications process, refer to Appendix D.

For an overview of how HBV and HCV PH-1600's received via REDCap will be handled, please refer to Appendix E.

Hepatitis A NBS Investigations

All persons who are immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV) positive should be entered into NBS. Due to the outbreak potential of hepatitis A (HAV), these reports should receive immediate follow-up. False positive IgM results are common and should be classified as 'not a case' in NBS.

For IgM anti-HAV positive persons with symptoms of an acute illness with discrete onset (e.g. fever, headache, malaise, anorexia, nausea, vomiting, diarrhea and abdominal pain with either jaundice or elevated liver enzymes), infection control measures should be implemented and the CEDEP Immunizations Program should be contacted immediately. To interrupt continued transmission, potential sources of infection and potentially exposed persons must be promptly identified and post-exposure prophylaxis must be given within 2 weeks of exposure.

For questions pertaining to HAV events or investigations, please contact either Robb Garman: Robb.Garman@tn.gov or Cassie Jones: Cassandra.Jones@tn.gov

Hepatitis B NBS Investigations

Acute HBV and perinatal HBV infections are reportable to the Health Department (HD).

In order to properly categorize cases of Hepatitis B infection, the public health regions should take the following steps upon receipt of all HBV lab reports, as well as clinical reports of suspected acute HBV:

1) Lab Management of HBV Lab Reports in NBS (performed by the Public Health Regions)

- Electronic Laboratory Reports (ELR):
 - All HBV laboratory reports are to be associated with a client/investigation and have a case status determined.
- Manual/Paper Laboratory Reports:
 - All pertinent paper laboratory reports (positive and negative) that support a case status determination need to be entered into NBS as a laboratory report and associated with the investigation.
 - For best practices, laboratory reports/results given over the phone should be supported by a paper laboratory report. If verbal laboratory results are given, please make every effort (via lab or provider) to obtain a paper copy of these results.

2) Field Investigations of HBV (performed by the Public Health Regions)

- All suspected acute HBV cases (based on clinician reporting or other risk factor or lab data received),
 and/or
- All women of reproductive age (11-50 years) to rule out pregnancy (even if known to have chronic infection)
 - Standardized Tools Aiding in Field Investigations of Suspected Acute (Appendix B):
 Provider Requesting Records letter, HBV/HCV Case Report Form, a letter for contacts to an acute HBV case or acute HCV case, Accurint Record Search Request Form, and Public Health Authority letter (if necessary)
 - Standardized Tools Aiding in Field Investigations of Women of Reproductive Age (Appendix B): Provider Requesting Records letter (if no existing HBV investigation), Provider Requesting Records Verifying Pregnancy Status letter (if existing HBV investigation), HBV/HCV Case Report Form, Accurint Record Search Request, and Public Health Authority letter, if necessary

Note: Detailed instructions for HBV lab management, creating an NBS investigation, determining case status, and conducting field investigations are described below.

- 1. To avoid creating duplicate patient records in NBS, search for the patient by looking up their Date of Birth (DOB), followed by the first common letters of the name (to account for multiple spellings of names, ex: Steven or Stephen you would search for 'Ste'):
 - a. When searching, names entered with all capital letters appear first, followed by those entered with both capital and lower case letters, followed by those entirely in lower case.

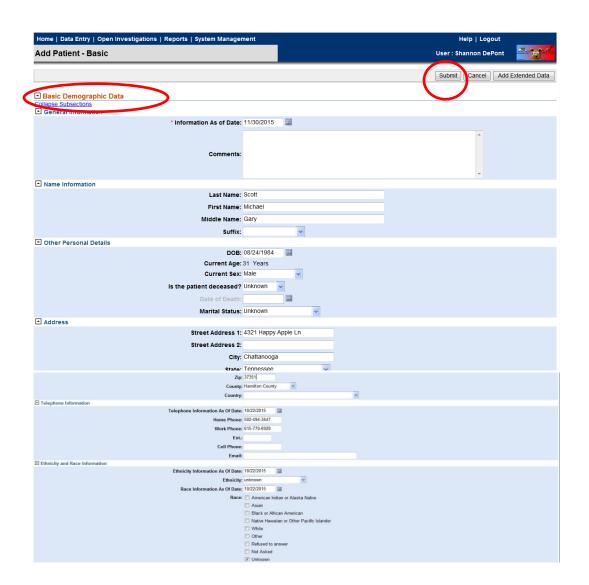


- i. If the patient has more than one NBS profile and needs to be merged, please send an email to Shannon.Depont@tn.gov with 'Merge Patient' in the Subject line and, in the email, include your DC# and the PSN/Patient ID. Shannon will determine if the patient meets the merging criteria.
 - 1. If there is an error in the name for one of the patient records, please correct the name before requesting the merge.
 - Do not send any additional information about the patients, such as patient name or date of birth. If this information is required, please contact Shannon De Pont via telephone at 615-532-8518.
 - When the NBS System Administrator merges the patient records, only one of the PSN numbers will be preserved and available when searching. Make note of all of the PSN numbers for the next step.
 - 4. After the patient records are merged, you will need to make sure there are not duplicate lab reports or investigations. All of the lab reports and investigations for the merged patients will now be listed in a single patient record. Follow the steps for managing duplicate lab reports or investigations, and ensure the appropriate associations are made.
- 2. Before creating an investigation for an Electronic Laboratory Report (ELR), check NBS for the patient as you would when manually entering a paper laboratory report.

- 3. If the patient is not in NBS, add them and their laboratory report(s) into NBS:
 - a. Click 'add a new patient':



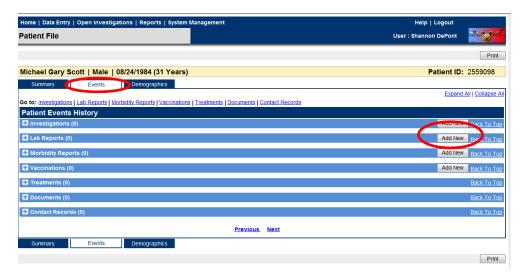
- i. Fill out any information appearing on the laboratory report.
- ii. Unless otherwise specified on the lab, mark the subsequent fields as follows:
 - 1. Information As of Date: Auto populates
 - 2. Comment: Skip/leave blank unless needed
 - 3. Is the patient deceased?: Unknown
 - 4. Marital Status: Unknown
 - 5. Full Address
 - a. County: Does not auto populate, please research via the following resources:
 - https://tools.usps.com/go/ZipLookupAction input
 - b. Census Tract: Skip/leave blank
 - 6. Phone/email: (if known)
 - 7. Ethnicity: Unknown
 - 8. Race: Unknown
- iii. Do not enter information for type, assigning authority, or ID Value
- iv. Click Submit.



If the patient is in NBS, click on their Patient ID:

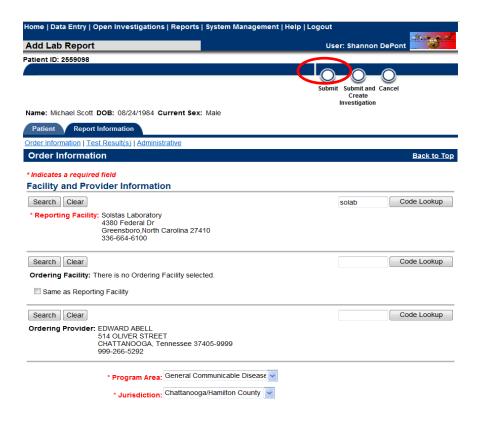


4. To add a lab, click on the events tab, then Add New next to Lab Reports:

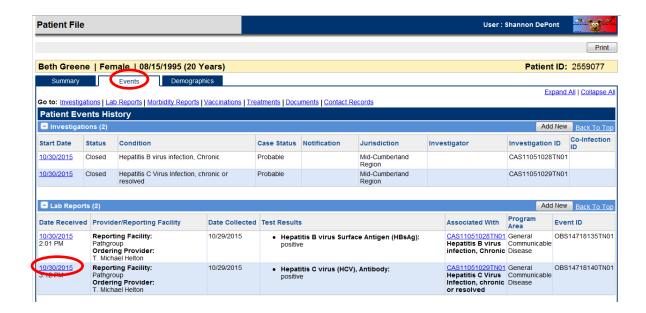


- a. When entering a lab (in a new jurisdiction) for an existing investigation (in a different jurisdiction), refer to step 26 on page 42 for guidance on transferring jurisdiction.
 - i. Mark the laboratory fields as indicated below:
 - 1. Reporting Facility (if facility is not found, refer to appendix C for instruction on adding an organization)
 - 2. Ordering Facility: Only if listed on lab (if facility is not found, refer to appendix C for instruction on adding an organization)
 - 3. Ordering Provider (if provider is not found, refer to appendix C for instruction on adding a provider)
 - 4. Program Area: General Communicable Disease
 - 5. Jurisdiction (auto populates based on county you entered in the previous step)
 - 6. Lab Report Date: Use the lab's resulted/verified/completed/report date
 - 7. Date Received by Public Health: Date you received the lab
 - 8. Ordered Test
 - a. Refer to NBS Lab Translator sheet (Appendix C), fill in corresponding result, and click Select.
 - 9. Accession Number: If given
 - 10. Specimen Source: Serum, unless otherwise specified
 - 11. Specimen Site: Skip (leave blank)
 - 12. Date Specimen Collected: Collection Date
 - 13. Patient Status at Specimen Collection: Unknown, unless otherwise specified
 - 14. Pregnant:
 - a. Unknown: If patient is female and has unknown pregnancy status
 - b. Pregnant: If patient is female and status is known to be pregnant

- c. Skip: If patient is male
- 15. Resulted test:
 - a. Refer to NBS Lab Translator sheet (Appendix C)
 - b. Fill in corresponding result
 - c. Click Add Test Result
- 16. Click Submit

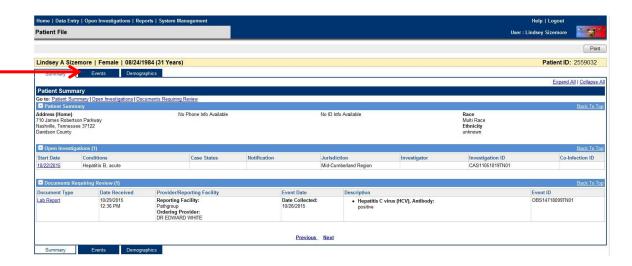


b. To edit a previously entered lab, click the events tab, and then date received. Click Edit





- Return To File; Eve
- If you receive both qualitative and quantitative results, please enter both
 results. However, if you receive both a numerical result and a log result for the
 same lab on the same date, please enter only the numerical result.
- ii. Click Submit
- 5. Prior to conducting your field investigation for newly reported HBV cases that are suspected of having acute HBV (clinician report, risk factors, associated labs), check to see if they have an existing HBV investigation by clicking on events:



- a. For those with an existing chronic HBV investigation:
 - i. Associate the lab with the chronic investigation even if the investigation has been closed and <u>case status should be updated</u>, if necessary. A second investigation should not be created unless:
 - 1. The patient is pregnant (refer to Hepatitis B Positive Pregnant Female section).
 - With pregnancy, the patient will have an acute and/or chronic investigation in addition to a pregnancy investigation for <u>each</u> pregnancy.
- b. For those with an existing acute HBV investigation:
 - i. If additional labs are received related to the acute hepatitis B condition, they should be associated with the existing hepatitis B acute investigation, even if the investigation has been closed, and <u>case status should be updated</u>, if necessary. A second investigation should not be created unless:
 - A positive/reactive lab report is received for another viral hepatitis infection (HCV, HAV)
 - a. Create an investigation for the additional viral hepatitis infection, acute or chronic, as appropriate.
 - 2. A positive lab report is received with collection date greater than <u>six</u> months from the date of collection of the first specimen (in the existing HBV acute investigation)
 - a. Create an investigation for a chronic HBV investigation.
 - 3. The patient is pregnant (refer to Hepatitis B Positive Pregnant Female section).
 - With pregnancy, the patient will have an acute and/or chronic investigation in addition to a pregnancy investigation for each pregnancy.
- c. For those with existing acute <u>and</u> chronic HBV investigations:
 - i. Associate the lab with the chronic investigation even if the investigation has been closed and <u>case status should be updated</u>, if necessary. A second investigation should not be created unless:
 - 1. The patient is pregnant (refer to Hepatitis B Positive Pregnant Female section).
 - With pregnancy, the patient will have an acute and/or chronic investigation in addition to a pregnancy investigation for each pregnancy.

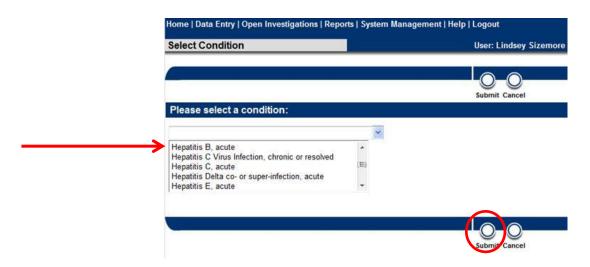
- d. For those with multiple existing acute or multiple existing chronic HBV investigations:
 - i. Refer to the earliest investigation and update the case status (if necessary), associate all HBV labs with this investigation, and change the case status for the repetitive HBV chronic investigations to 'not a case.'
 - Example: if you have a chronic HBV investigation with an investigation start date of 6/17/2006 and another with an investigation start date of 9/30/2011, you will update the case status for the 6/17/2006 investigation (if necessary), associate all HBV labs to the 6/17/2006 investigation, and change the case status for the 9/30/2011 investigation to 'not a case.' This will ensure our case counts to CDC are correct.
 - a. Going forward, there should not be multiple chronic investigations created. In the past, this was the practice in some regions to account for pregnancy; however, we now have the Hepatitis B Positive Pregnant Female condition (refer to Hepatitis B Positive Pregnant Female section).
- 6. To create a **HBV** investigation, click Add New:



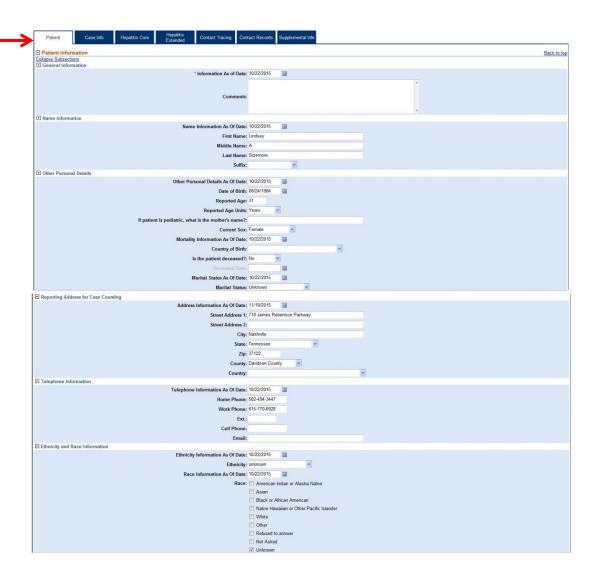
- a. <u>For condition, select acute, HBV if you are preparing to do a field investigation.</u>

 <u>Otherwise, select chronic, hepatitis B</u> and click SUBMIT.
 - i. In the prior NBS Hepatitis pages, you could only select "Hepatitis" as the condition and you would modify the diagnosis within the investigation to reflect "hepatitis B, acute" or "hepatitis B, chronic" prior to closing the investigation.
 - ii. "Hepatitis" is still an option for condition; however, we request that you choose the specific condition (hepatitis B, acute or hepatitis B, chronic) from the beginning.

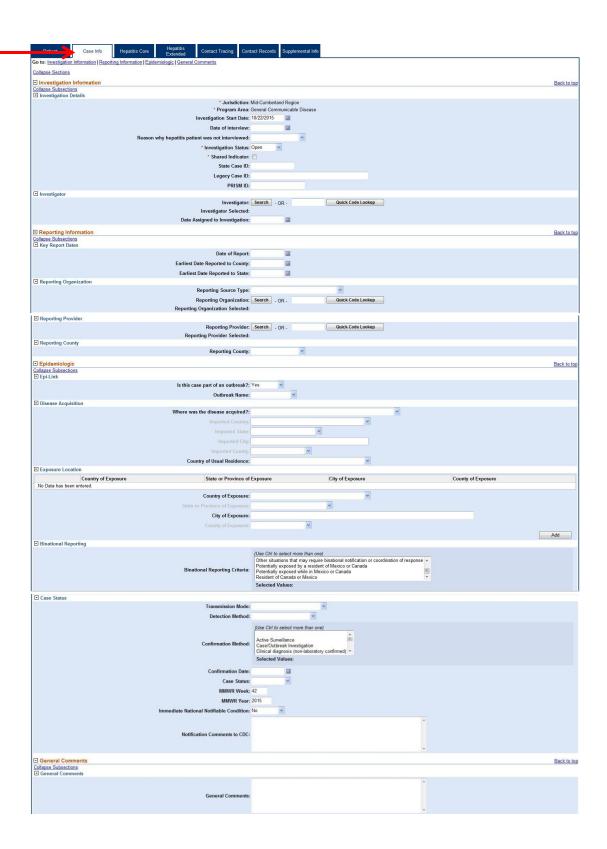
iii. The condition you choose from the beginning makes a difference in which extended tabs you will have access to.



- iv. If the condition selected is acute, you are planning to conduct a field investigation, which includes sending out the provider requesting records letter (Appendix B).
- v. Once the provider requesting records letter is received back, you can use this information to fill out the case report form (Appendix B). This will be used to populate the NBS tabs discussed below.
- 7. Under the Patient tab, data is pre-populated based on the information within the patient's NBS record (assuming the information was present in patient's record):
 - a. If you are aware that any of the patient's information has changed, update it within the investigation. This will update the information within the NBS record to reflect the most current information. More importantly, it will keep both the past and present information in the record for historical context.
 - You should only update this information within the investigation under the Patient tab (see below). DO NOT update this information in the Demographics tab on the Patient home screen as this will impact the historical data within NBS.

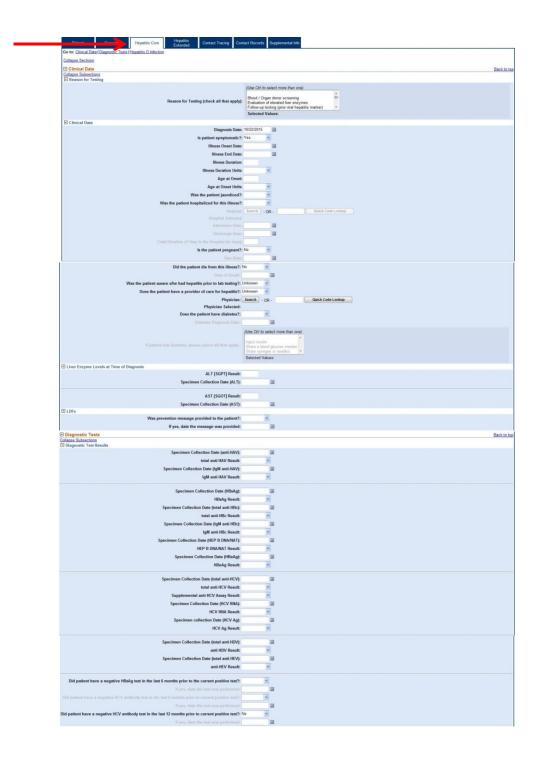


- 8. Under the Case Info tab, the Jurisdiction, Program Area, Investigation Start Date, Investigation Status, MMWR Week, MMWR Year, and Immediate National Notifiable Condition are prepopulated based on the information within the patient's NBS record (assuming the information was present in patient's record) and are based on the date you open the investigation:
 - a. You will fill out the following information for surveillance purposes:
 - i. Date of Interview (if patient was interviewed)
 - ii. Reason why patient was not interviewed (if patient was not interviewed)
 - iii. Investigator (Search for yourself or enter your quick code)
 - iv. Date Assigned to Investigation use the date you were assigned the investigation
 - v. Reporting Source Type (the type of facility that reported the case), if known. If not known, leave blank.
 - vi. Is this case part of an outbreak?
 - 1. If yes, select the outbreak name (central office will assign an outbreak name if this occurs)
 - vii. Where was this disease acquired, if known? If not known, leave blank.
 - viii. Country of Usual Residence (if outside of the United States)
 - ix. Country of Exposure (if outside of the United States)
 - x. Detection Method
 - xi. Case Status 'suspect' can be selected initially while waiting to receive the provider requesting records letter back; however, it must be changed to reflect the appropriate case status (Appendix A) prior to closing the investigation.
 - xii. General Comments this is where you will put any additional information gathered from the field investigation that you feel are pertinent.
 - For example, if a patient indicates they share body jewelry, you would indicate that here as it isn't captured elsewhere in the NBS investigation.

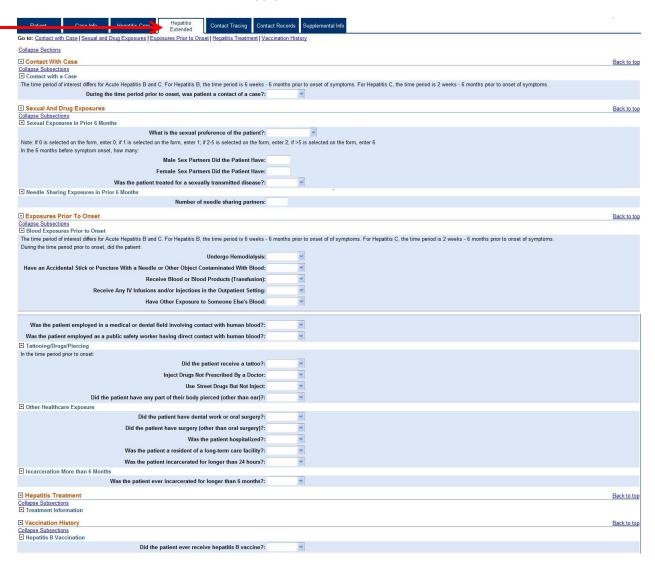


- 9. The Hepatitis Core tab appears within the investigation for all hepatitides.
 - a. Central Office will interpret those items with unknown selected to mean the patient was lost to follow-up or refused to answer.
 - b. Central Office will interpret those items with nothing selected (blank) to mean the case is still being worked up and the field investigation is not complete.
 - c. You will fill out the following information for surveillance purposes:
 - i. Reason for Testing (check all that apply)
 - ii. Diagnosis Date use the lab's resulted/verified/completed/report date (same as the resulted date when the lab is entered)
 - iii. Is patient symptomatic? If yes, and if known:
 - 1. Illness Onset Date
 - iv. Was the patient jaundiced?
 - v. Was the patient hospitalized for this illness? If yes, and if known:
 - 1. Hospital's information
 - 2. Admission Date
 - 3. Discharge Date
 - vi. Is the patient pregnant? If yes,
 - 1. Due Date
 - A second, separate pregnancy investigation must be opened in NBS to denote the pregnancy (refer to Hepatitis B Positive Pregnant Female Section). The patient will have their original Hepatitis investigation(s) and their pregnancy investigation(s).
 - vii. Did the patient die from this illness? If yes, and if known:
 - 1. Date of Death
 - a. You must be certain the patient died from the hepatitis indicated as the investigation condition and not from another primary cause.
 - viii. Was the patient aware s/he had hepatitis prior to lab testing?
 - ix. Does the patient have a provider of care for hepatitis? If yes, and if known:
 - 1. Physician's information
 - x. Does the patient have diabetes? If yes, and if known:
 - 1. Diabetes diagnosis date
 - a. If you only know the year, please denote the appropriate year and use 01/01 for the month and day, respectively.
 - 2. If patient has diabetes, select all that apply
 - xi. Fill in any lab results that pertain to the labs you have entered (or were imported via ELR) that will be associated with this investigation.
 - 1. While all positive paper laboratory reports need to be entered and associated, the only HBV antibody labs available in the Hepatitis Core tab are total anti-HBc and IgM anti-HBc.

2. For numeral xi section only, if there is information you do not know, you can leave the fields blank. You do not need to select Unknown, except for IgM anti-HBc result.



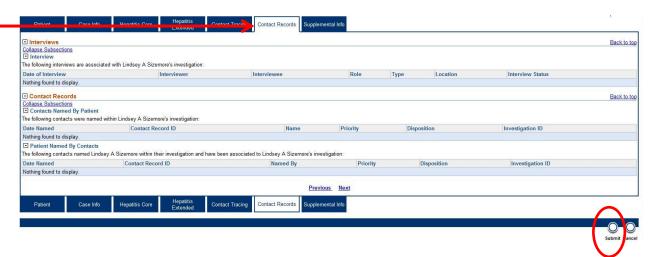
- 10. The Hepatitis Extended tab appears within the investigation and differs depending on what Hepatitis condition was selected when opening the investigation. All known fields in this tab must be filled out after conducting the "hepatitis B, acute" field investigation. If you determine after the field investigation that, based on the information you acquired, the patient meets the case definition for "hepatitis B, chronic" as opposed to "hepatitis B, acute", refer to step 29 on page 46 for how to change the condition to "hepatitis B, chronic".
 - a. Contact with a Case asks if the patient was aware that they were a contact to a known case of HBV. If you select yes, NBS asks for the type of contact the patient had with that individual (sexual, needle, household, or other). If other is selected, please specify the type of contact in the text box.
 - i. In the Hepatitis Extended tab, some fields will not populate unless yes is selected. For example, if you select Yes for "Did the patient receive a tattoo?" another set of questions will appear asking where the tattooing was performed (check all that apply).



- 11. Under the Contact Tracing tab, you are trying to determine who the patient could have exposed to HBV and contact tracing should be conducted on all acute HBV cases. You will fill out the following information for surveillance purposes:
 - a. Infectious Period From 6 weeks prior to the onset date
 - b. Infectious Period To 60 days after the onset date
 - i. Onset symptoms or, in absence of symptoms, the first positive lab
 - ii. http://www.timeanddate.com/date/dateadd.html
 - c. Contact Investigation Status (mark as open until all contacts have been interviewed) and then close.
 - d. Contact Investigation Comments this is where you will put any additional information gathered from the field investigation that you feel are pertinent.

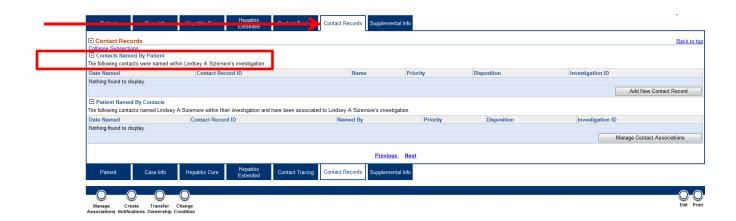


12. Under the Contact Records tab, you must submit the investigation before you can add a contact.



- 13. Once you submit, select the contact records tab again. You will fill out the following information for surveillance purposes:
 - a. Contacts Named by Patient: These are persons that the case you are investigating has named as contacts during their infectious period.
 - i. Add all named contacts.
 - b. Patients Named by Contacts: These are persons that named the case you are investigating as a possible contact.
 - i. Prepopulates from the record(s) of these contacts. If you are adding a new investigation, this field will be blank. You do not need to do

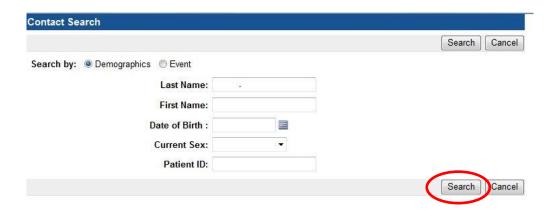
Remember: Always protect the confidentiality of the index patient's identity when interviewing contacts.



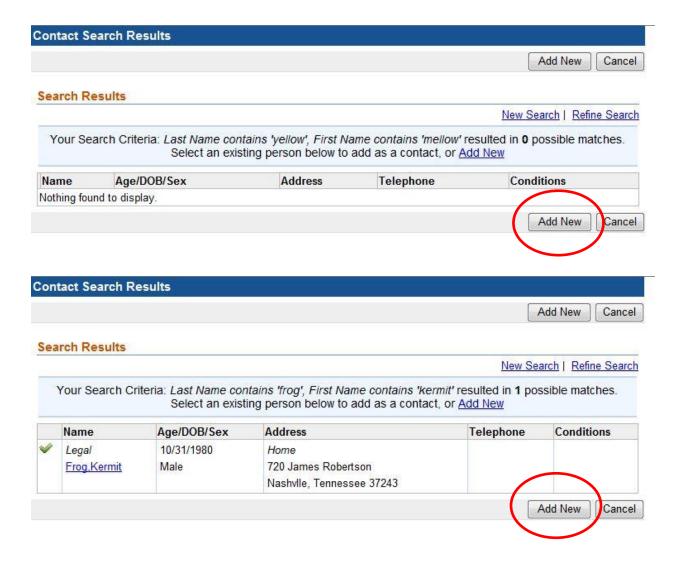
14. To add a new contact record, select Add New Contact Record:



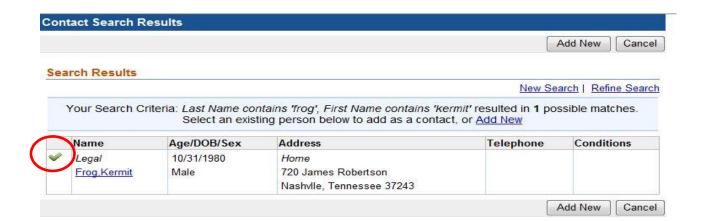
- 15. To avoid creating duplicate patient records in NBS, search for the patient by looking up their Date of Birth (DOB), followed by the first common letters of the name (to account for multiple spellings of names, ex: Steven or Stephen you would search for 'Ste'):
 - a. Names entered with all capital letters appear first, followed by those entered with both capital and lower case letters, followed by those entirely in lower case.



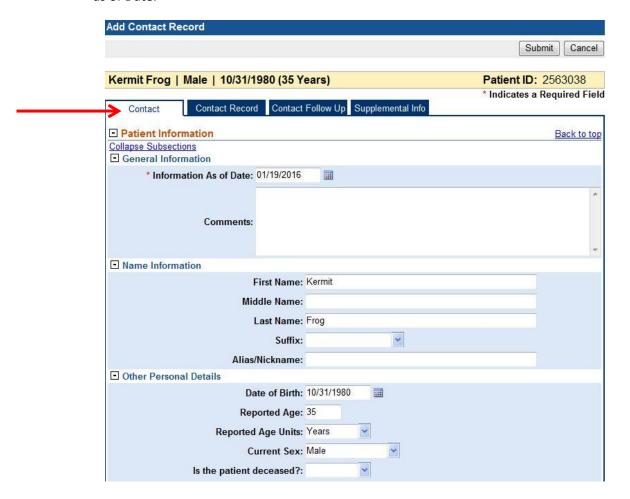
16. If the patient does not exist in NBS (or if you are not sure it is the same person), select Add New and add any known demographic information.

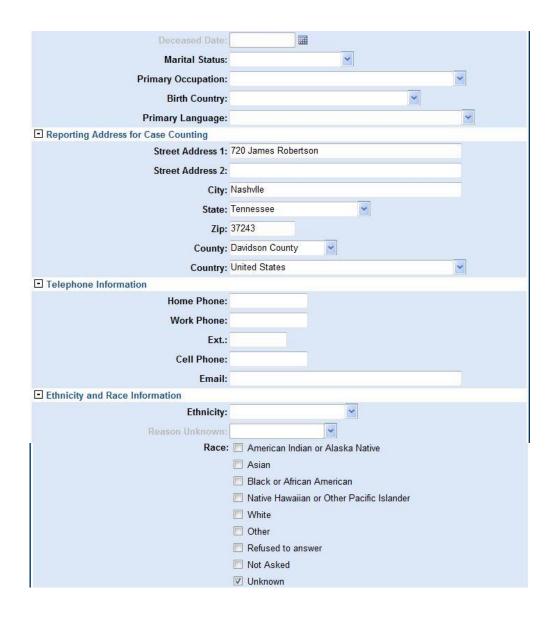


- 17. If the patient is in NBS, select the green check mark next to their name
 - a. This will populate four additional tabs for the contact patient: Contact, Contact Record, Contact Follow Up, and Supplemental Info.

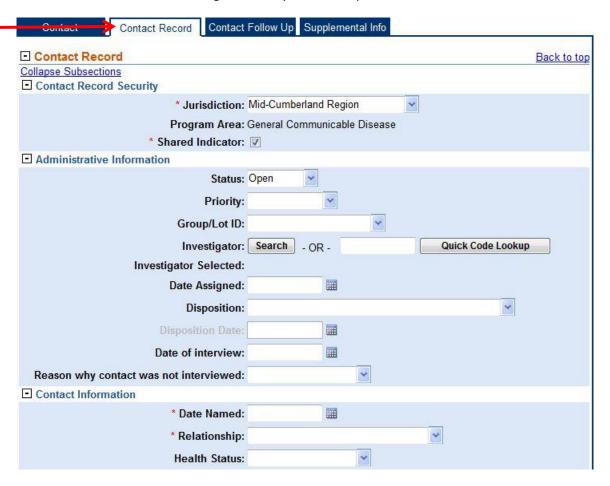


- 18. Under the Contact tab, all patient information that exists in the NBS record will populate.
 - a. Update any information that has changed and/or any new information.
 - b. Most of the information in the contact record cannot be filled out until you have interviewed the contact.
 - i. You can still add a contact record and reopen the record to add the information obtained from the interview. If you do this, be sure to change the 'Information as of Date.'





- 19. Under the Contact Record tab, fill out the following:
 - a. Investigator (Search for yourself or enter your quick code)
 - b. Disposition
 - c. Date of Interview
 - d. Reason why contact was not interviewed, if applicable
 - e. Date Named (date contact was named by index patient)
 - f. Relationship
 - g. Exposure Type
 - i. If Other Needle Sharing type is selected, enter the type of needle sharing
 - h. First Exposure Date, if known
 - i. Last Exposure Date, if known
 - j. General Comments this is where you will put any additional information gathered from the field investigation that you feel are pertinent.





20. Under the Contact Follow Up tab, fill out any of the information you know after conducting the interview:



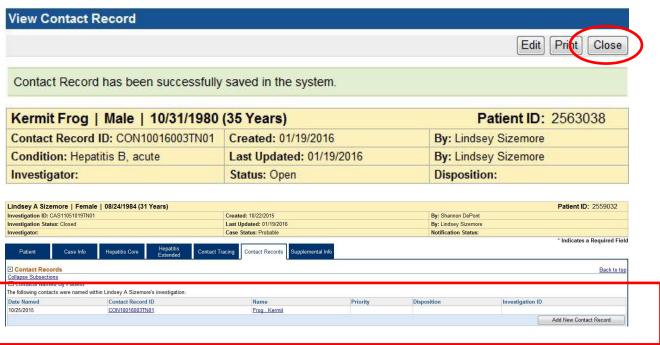
21. Under the Supplemental Info tab, you are not required to enter any information; however, you can use this as a place to upload the HBV/HCV Case Report form or any other supporting documentation from your investigation.



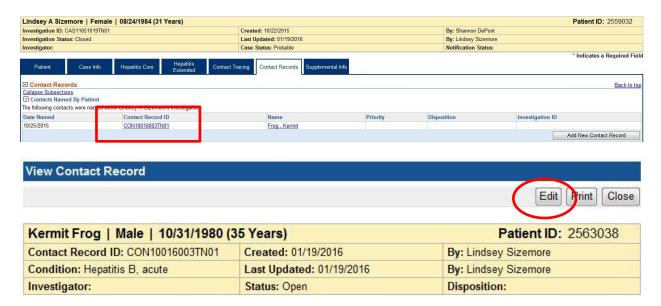
22. Once all tabs within the contact record have been filled out, click on the Contact Record tab, change the contact record status to closed, and click SUBMIT. This will save the contact record.



- a. Select close to close the contact record. This record is now listed under the original patient as a contact.
- b. To add additional contacts, follow the same steps as above.



23. To edit or add additional information within a contact record, click on the Contact Record ID, click Edit, update the contact record accordingly, and click Submit.



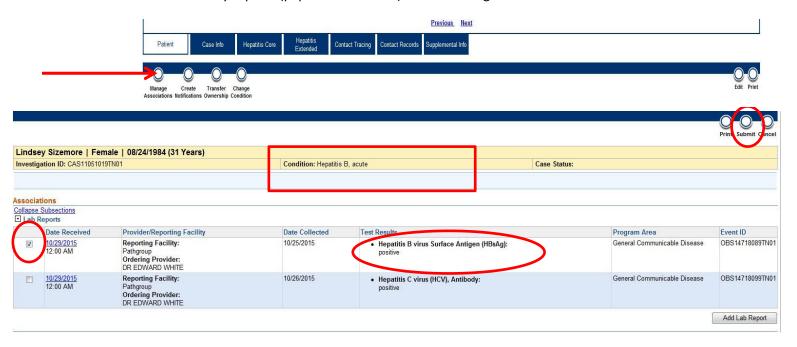
- 24. If you need to change information within an investigation, you can go back into the <u>investigation</u>, click Edit, update the Investigation information accordingly, and click SUBMIT.
 - a. Under the Supplemental Info tab, you are not required to enter any information; however, you can use this as a place to upload the HBV/HCV Case Report form or any other supporting documentation from your investigation.



Go to: Associations | Notes and Attachments | History | Custom Fields

Collapse Sections

25. Once the investigation has been submitted, click on Manage Associations to associate relevant HBV laboratory reports (paper or electronic) to the investigation and click SUBMIT.



Out of Tennessee Procedure

Out of Tennessee Paper Laboratory Reports

- Does the patient have an existing non-perinatal Hepatitis B or Hepatitis C NBS investigation?
 - If Yes
 - Transfer jurisdiction to Out of Tennessee, denote the appropriate state (and patient address) where the information will need to be transferred to on laboratory report, and send laboratory report to central office:

Tennessee Department of Health
Andrew Johnson Tower - HIV/STD/Viral Hepatitis Section – 4th Floor
Attention: Shannon De Pont
710 James Robertson Parkway
Nashville, TN 37243

- o If No
 - Send paper laboratory report to central office:

Tennessee Department of Health
Andrew Johnson Tower - HIV/STD/Viral Hepatitis Section – 4th Floor
Attention: Shannon De Pont
710 James Robertson Parkway
Nashville, TN 37243

Viral Hepatitis staff will coordinate with Surveillance Systems and Informatics Program (SSIP) to alert appropriate state.

Out of Tennessee Electronic Laboratory Reports (ELR)*

- Does the patient have an existing non-perinatal Hepatitis B or Hepatitis C NBS investigation?
 - o If Yes
 - The investigation status needs to be marked as Open, which allows the investigation to show in the Open Investigations Queue.
 - Associate any relevant laboratory reports with this investigation (ELR and any existing paper laboratory reports).
 - Select 'Edit' in the investigation and update the demographic information in the
 'Patient' tab to reflect the address for the other jurisdiction.
 - As a reminder, change the demographics within the investigation and NOT in the Demographics tab, as the demographics you enter in the investigation will transfer to the Demographics tab.
 - Select 'Transfer Ownership' and change the jurisdiction to Out of Tennessee.
 - The investigation will show in the Open Investigation Queue under the Out of Tennessee jurisdiction for the SSI program to send the investigation and associated labs on to the new state or territory. Once the investigation has been forwarded on, the SSI program will change the case status to Not a Case and the investigation status to Closed.

An email needs to be sent notifying the SSI program about the transfer only if the investigation status has been changed to Closed, because the investigation will not show in the Open Investigations Queue. Then, email CEDS.Informatics@tn.gov with the Investigation ID (CAS#).

o If No

- Select 'Edit' in the lab report.
- Update the patient address in the lab report.
 - For manual labs, the demographic information may be updated in the Patient tab.
 - For electronic lab reports, the address will need to be added as Add Comment under Lab Report Comments toward the bottom of the lab report.



- Select 'Transfer Ownership' and change the jurisdiction to Out of Tennessee
 - If the lab was <u>NOT</u> marked as reviewed, and you can still see the Mark
 as Reviewed button, the receiving Surveillance Systems and Informatics
 (SSI) Program at the Central Office will see the lab report in their
 'Documents Requiring Review' work queue to be able to send the report
 to the new state or territory.
 - If the lab was marked as reviewed, notify Surveillance Systems and Informatics Program (SSIP) by emailing the Patient ID Number/PSN to <u>CEDS.Informatics@tn.gov</u> and they will alert the respective state.
 - Note: This is only required for Hepatitis B ELR. Hepatitis C ELR will continue to be marked as reviewed and Central Office Viral Hepatitis staff will coordinate with the Surveillance Systems and Informatics Program to address these.

In-State Procedure

In-State Paper Laboratory Reports

In-State Investigations must be transferred to the jurisdiction listed on the most recent laboratory report received.

- Does the patient have an existing non-perinatal Hepatitis B or Hepatitis C NBS investigation?
 - o If Yes
 - Associate any relevant laboratory reports with this investigation (ELR and any existing paper laboratory reports)
 - Coordinate with the appropriate jurisdiction, using Patient ID, to:
 - Transfer the investigation

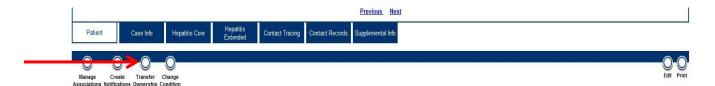
- Deliver paper laboratory reports not in NBS
- Update the address within the investigation to the new address, including the county
- o If No
 - Open an investigation following Viral Hepatitis investigation protocol
 - Coordinate with the appropriate jurisdiction to:
 - Deliver paper laboratory reports not in NBS

In-State Electronic Laboratory Reports (ELR)*

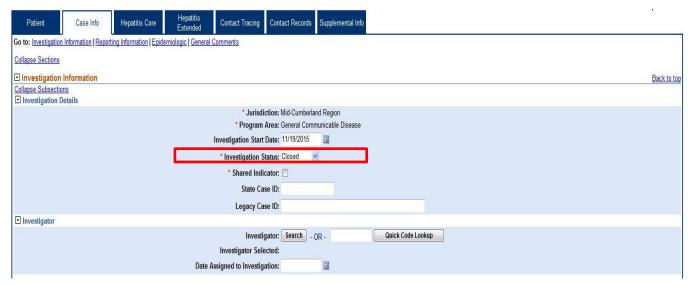
- Does the patient have an existing non-perinatal Hepatitis B or Hepatitis C NBS investigation?
 - If Yes
 - Associate any relevant laboratory reports with this investigation (ELR and any existing paper laboratory reports)
 - Coordinate with the appropriate jurisdiction, using Patient ID, to:
 - Transfer the investigation
 - Update the address in the investigation to the new address, including the county
 - o If No
 - Open an investigation following Viral Hepatitis investigation protocol

*Note: This is only required for Hepatitis B ELR. Hepatitis C ELR will continue to be marked as reviewed and Central Office Viral Hepatitis staff will coordinate with the Surveillance Systems and Informatics Program to address these.

The "ownership" of the investigation can be changed by clicking on Transfer Ownership at the top of the investigation and transferring the investigation to the correct jurisdiction.



- 27. Investigations must be closed <u>within 30 days</u> of the Investigation Start Date and a case status must be denoted.
 - a. To close the investigation, click on the Case Info tab and change the Investigation Status to "Closed."
 - b. To assign a case status per the CDC/CSTE case definition (Appendix A), click on the Case Info tab and select the appropriate case status.
 - i. During the 30 days while the case is being worked up, a case status of 'Suspect' is appropriate as a placeholder; however, NO cases should be closed with a case status of 'Suspect.'
 - 1. Select the case status based on the information you have at 30 days.
 - 2. The case status can be changed later should you acquire additional information.

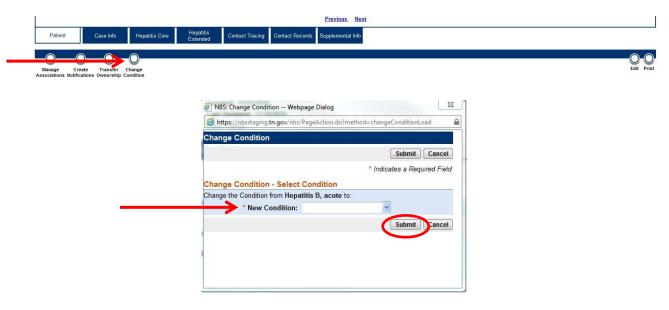




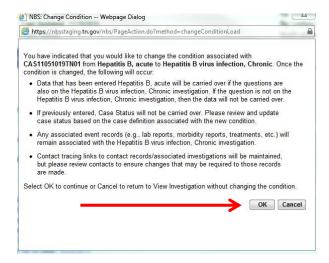
- 28. <u>A notification must be sent for each condition</u>. To do this, select Create Notifications and then select SUBMIT. <u>Refer to Appendix D for more detailed guidance on the Case Notifications Procedure.</u>
 - a. You should do this when submitting when you are closing the investigation to signal to Central Office that you are ready for the case to be reviewed.
 - b. <u>Do NOT create a notification for investigations with an Out of Tennessee jurisdiction or</u> those with a case status of 'Not a Case'.
 - c. Any changes made to the investigation after the CDC notification has been sent will automatically be sent to CDC. There is no need to create another notification.
 - i. Any comments added in the notification comments will be transferred to CDC.



- 29. If after conducting the field investigation it is determined the patient was a case of "hepatitis B, chronic" instead of "hepatitis B, acute", select Change Condition, select the correct Condition and SUBMIT.
 - a. This patient would not be "hepatitis B, acute" with a case status of 'Not a Case. They need to have their condition changed to "hepatitis B, chronic" with a case status of either 'Confirmed' or 'Probable.' It is critically important to change the condition and designate the appropriate case status for CDC reporting purposes.



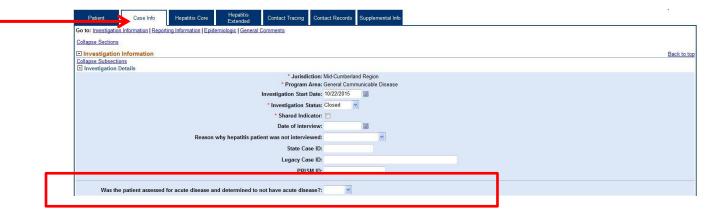
b. When changing conditions, you will get the following warning message. This is letting you know that the previous condition selected will not carry over, any events (laboratory reports) you associated will remain associated, and any contact tracing links will be maintained. Most importantly, however, it is letting you know that any information currently under the "hepatitis B, acute" extended tab that is not also in the "hepatitis B, chronic" extended will not transfer over. Select OK.



c. The Hepatitis Extended tab will now be populated with the "hepatitis B, chronic" fields and the additional information will need to be filled out.



i. In a situation where you change the condition from acute to chronic, under the Case Info tab, select 'Yes' for the question 'Was the patient assessed for acute disease and determined to not have acute disease?"



Notes Regarding HBV Investigations

With respect to HBV, patients should have no more than one investigation for an acute infection and one investigation for a chronic infection. Creating multiple investigations for acute or chronic HBV affects case count information reported to CDC.

HBV Electronic Laboratory Reports (ELR) MUST be associated with an existing investigation or an investigation must be created. Do <u>NOT</u> mark them as reviewed, as this creates orphan HBV laboratory reports.

If you receive an isolated positive IgM anti-HBc, anti-HBc, anti-HBs, or anti-HBe, please refer to the HBV antibody table in Appendix B for case classification instructions.

If you receive paper laboratory reports with more than one hepatitis test listed (i.e. a laboratory report with both HBV and HCV tests), please make a copy for yourself and mark out the HBV tests prior to sending the laboratory report to central office. Failure to do so may result in you receiving the HBV labs back, as central office administrative staff will not know the HBV labs have been entered.

If in doubt about whether or not to create an investigation or how to associate an ELR, please contact your Central Office Epidemiologist:

Lindsey Sizemore: lindsey.sizemore@tn.gov or 615-770-6928 (CHR, SER, SUL)

Jennifer Black: jennifer.black@tn.gov or 615-253-4782 (ETR, KKR, NER)

Travis Sondgerath: travis.sondgerath@tn.gov or 615-253-4452 (MCR, NDR, UCR)

Epidemiologist I - TBD (JMR, SCR, MSR, WTR)

If you need an Accurint search for a Hepatitis case, please fill out the form in Appendix B and send securely to Jennifer Black: jennifer.black@tn.gov

Hepatitis B Positive Pregnant Female NBS Investigations

All pregnant women must be serologically screened for hepatitis B virus (HBV) infection for every pregnancy. If a reproductive age woman has a marker of current infection (HBsAg, HBeAg, HBV DNA, IgM anti-HBc), regardless of HBV condition (acute, chronic)or case status (confirmed, probable), she should be field investigated for pregnancy status.

In order to properly categorize cases of Hepatitis B infection, the public health regions should take the following steps upon receipt of all HBV lab reports, as well as clinical reports of suspected acute HBV:

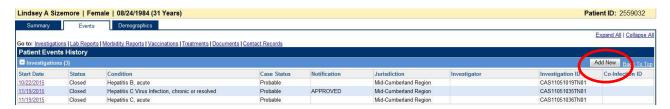
1) Lab Management of HBV Lab Reports in NBS (performed by the Public Health Regions)

- Electronic Laboratory Reports (ELR):
 - All HBV laboratory reports are to be associated with a client/investigation and have a case status determined.
- Manual/Paper Laboratory Reports:
 - All pertinent paper laboratory reports (positive and negative) that support a case status determination need to be entered into NBS as a laboratory report and associated with the investigation.
 - For best practices, laboratory reports/results given over the phone should be supported by a paper laboratory report. If verbal laboratory results are given, please make every effort (via lab or provider) to obtain a paper copy of these results.

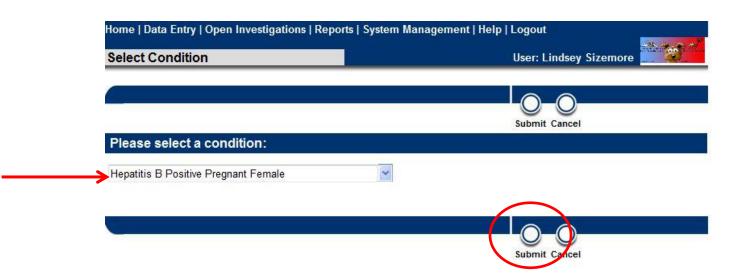
- 2) <u>Field Investigations of HBV</u> (performed by the Public Health Regions)
 - All women of reproductive age (11-50 years) to rule out pregnancy (even if known to have chronic infection)
 - Standardized Tools Aiding in Field Investigations of Women of Reproductive Age
 (Appendix B): Provider Requesting Records letter (if no existing HBV investigation),
 Provider Requesting Records Verifying Pregnancy Status letter (if existing HBV
 investigation), HBV/HCV Case Report Form, Accurint Record Search Request Form, a
 letter for contacts to an acute HBV or acute HCV case, and Public Health Authority
 letter, if necessary

Note: Detailed instructions for creating an NBS investigation, determining case status, and conducting field investigations are described below.

- 1. Be sure the patient's acute and/or chronic investigation(s) are in NBS (if not, refer to Hepatitis B NBS Investigations section).
 - a. After the appropriate HBV investigation has been identified or entered, navigate to the Events Tab, and click Add New:

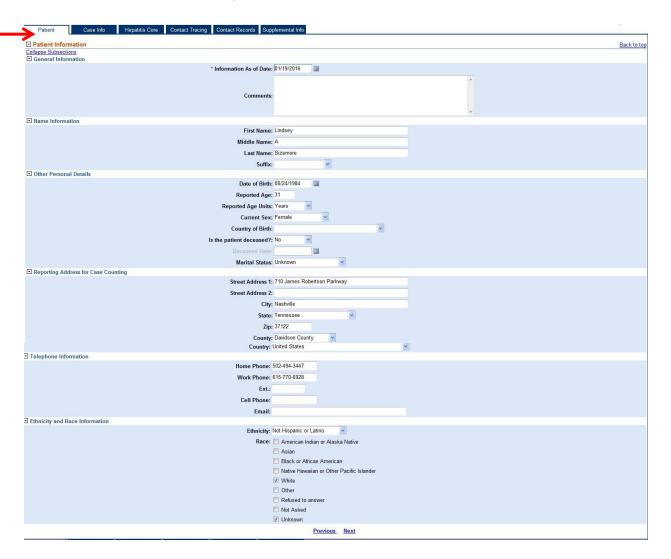


2. For condition, select acute, hepatitis B Positive Pregnant Female and click Submit.



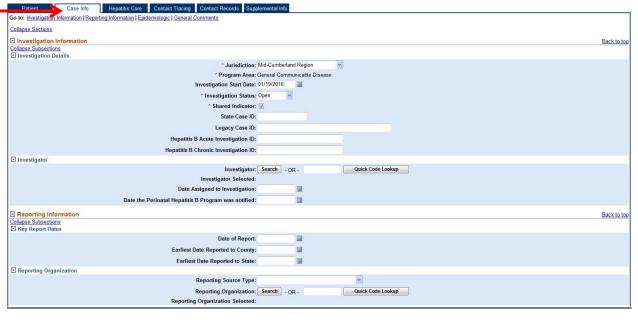
3. Under the Patient tab, the following data is pre-populated based on the information within the patient's NBS record (assuming the information was present in patient's record):

- a. If you are aware that any of the patient's information has changed, update it within the investigation. This will update the information within the NBS record to reflect the most current information. More importantly, it will keep both the past and present information in the record for historical context.
- b. You should only update this information within the investigation under the Patient tab (see below). DO NOT update this information in the Demographics tab on the Patient home screen as this will impact the historical data within NBS.



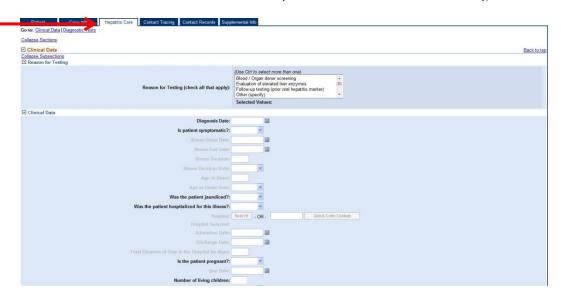
- 4. Under the Case Info tab, the Jurisdiction, Program Area, Investigation Start Date, Investigation Status, MMWR Week, and MMWR Year are pre-populated based on the information within the patient's NBS record (assuming the information was present in patient's record) and are founded on the date you open the investigation:
 - a. You will ONLY need to fill out the following information for surveillance purposes:
 - i. State Case ID the REDCap number assigned by the Perinatal Hepatitis B Coordinator

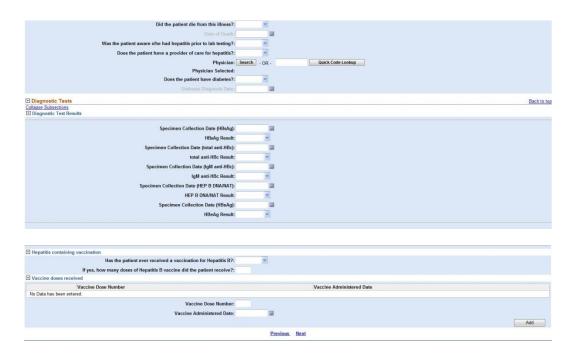
- ii. Hepatitis B Acute Investigation ID and/or Hepatitis B Chronic Investigation ID
 - 1. This is the investigation ID number and starts with "CAS"
- iii. Investigator (Search for yourself or enter your quick code)
- iv. Date the Perinatal Hepatitis B Program was notified
- v. General Comments this is where you will put any additional information gathered from the field investigation that you feel are pertinent.



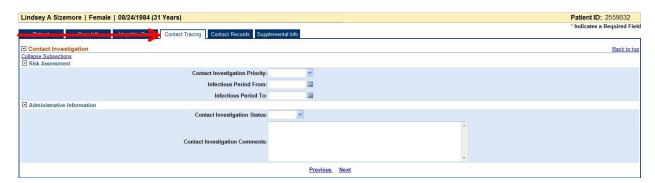


- 5. The Hepatitis Core tab appears within the investigation for all hepatitides.
 - a. You will need to fill out the following information for surveillance purposes (note: for unknown, select unknown from the drop down):
 - i. Reason for Testing (check all that apply), if known
 - ii. Is the patient pregnant? Enter YES (you would not have opened the investigation if she wasn't).
 - 1. Enter the Due Date and the number of living children (if known)
 - iii. Fill in any lab criteria that pertain to the most recent HBV lab if a HBV lab was not conducted as part of a pregnancy panel. If a lab was conducted as part of a pregnancy panel, refer to that lab.
 - 1. For the iii section only, if there is information you do not know, you can leave the fields blank. You do not need to select Unknown.
 - iv. Has the patient ever received a vaccination for Hepatitis B?
 - 1. If yes, how many does of Hepatitis B vaccine did the patient receive?
 - v. Vaccine Dose Number (most recent vaccine of the series), if known
 - vi. Vaccine Administered Date (most recent vaccine of the series), if known





6. Under the Contact Tracing tab, you are not required to enter any information.



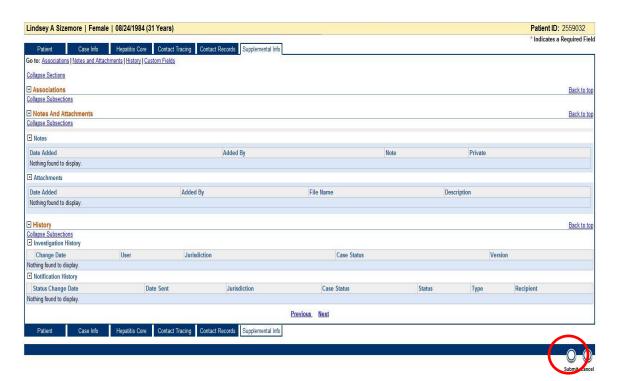
7. Under the Contact Records tab, you are not required to enter any information.



8. Under the Supplemental Info tab, you are not required to enter any information; however, you can use this as a place to upload any supporting documentation from your investigation.



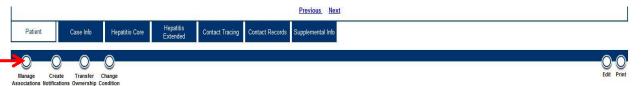
9. Once all tabs within the investigation have been filled out, click SUBMIT. This will save the investigation.



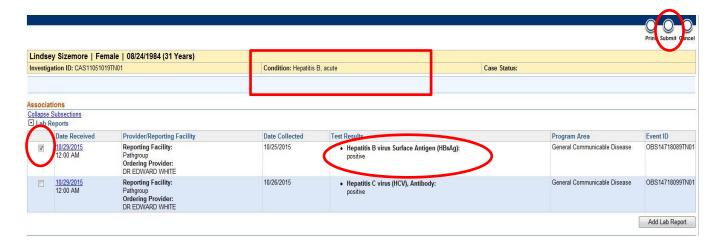
 a. If you need to change information within an investigation, you can go back into the investigation, click Edit, update the Investigation information accordingly, and click SUBMIT.



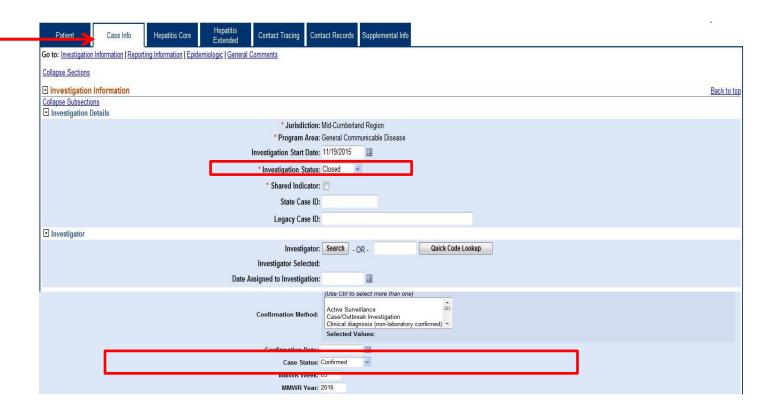
10. Once the investigation has been submitted, click on Manage Associations to associate hepatitis B laboratory reports (paper or electronic) related to the current pregnancy to the investigation:



- a. Select the most recent HBV lab and click Submit.
 - The most recent lab will be associated with the HBV chronic investigation (or the acute investigation in the absence of a chronic investigation) AND the Hepatitis B Positive Pregnant Female investigation.



- 11. Investigations must be closed within 30 days of the Investigation Start Date and a case status must be denoted.
 - a. To close the investigation, click on the Case Info tab and change the Investigation Status to "Closed."
 - b. To assign a case status, click on the Case Info tab and select the appropriate case status.
 - i. The case status should be 'confirmed' for all Hepatitis B positive pregnant female investigations. (You wouldn't have opened the investigation if they weren't pregnant).
 - c. Click Submit



- 12. <u>Please do NOT send a notification for this condition</u>. To do this, select Create Notifications and then select SUBMIT. <u>Refer to Appendix D for more detailed guidance on the Case Notifications</u> Procedure.
 - a. You should do this when you are closing the investigation to signal to Central Office that you are ready for the case to be reviewed.
 - i. <u>Do NOT create a notification for investigations with an Out of Tennessee</u> jurisdiction or those with a case status of 'Not a Case.'
 - b. Any changes made to the investigation after the CDC notification has been sent will automatically be sent to CDC. There is no need to create another notification.
 - i. Any comments added in the notification comments will be transferred to CDC.



Notes Regarding Hepatitis B Positive Pregnant Female Investigations

With respect to HBV, patients should have no more than one investigation for an acute infection and one investigation for a chronic infection. Creating multiple investigations for acute or chronic affects case count information reported to CDC.

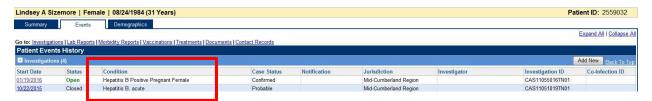
If a reproductive age woman has a marker of current infection (HBsAg, HBeAg, HBV DNA, IgM anti-HBc), regardless of HBV condition (acute, chronic) or case status (confirmed, probable), she should be field investigated for pregnancy status. Even if you receive a laboratory such as 'HBV DNA not detected', the patient should still be assessed for pregnancy.

<u>Each pregnancy is a new event – Hepatitis B, Positive Pregnant Female.</u> As a result, you must open a <u>new investigation for each pregnancy with the condition 'Hepatitis B, Positive Pregnant Female.'</u> Do not enter a second chronic investigation to denote pregnancy.

If a patient is investigated for pregnancy status and found not to be pregnant, please denote this in the general comments of the HBV investigation with the date the pregnancy investigation was conducted.

For example, a patient could have three pregnancy HBV investigations, denoting each of their three pregnancies, as well as an acute and/or chronic HBV investigation. There should only be one acute and/or one chronic investigation but there can be multiple HBV pregnancy investigations.

In the example below, there is one HBV acute investigation and one Hepatitis B Positive Pregnant Female Investigation. This tells us that the patient was diagnosed with HBV while in her acute stage and she hasn't had additional lab reports that were greater than six months from the collection date of the lab report associated with her acute HBV investigation. Additionally, this tells me she has been pregnant one time while being positive for HBV since the implementation of the Hepatitis B Positive Pregnant Female condition in 2016.



If in doubt about whether or not to create an investigation or for any other questions regarding Hepatitis B Positive Pregnant Females, please contact Janice Johnson: M.Janice.Johnson@tn.gov or 615-253-1359.

Hepatitis B Positive Pregnant Female NBS and Field Investigations

You get a Positive Lab of Current Infection (HBsAg, HBeAg, HBV DNA, or IgM anti-HBc) For a Woman of Reproductive Age (11-50)**Does the Patient Have an existing NBS** Investigation? If no: If yes: 1. Open an investigation with the 1. Add the laboratory report and appropriate condition (field update case status (if necessary). investigating if acute). 2. Conduct a field investigation to 2. Conduct a field investigation to determine if the patient is pregnant. determine if the patient is pregnant. **Is Patient Pregnant?** If yes: If no: * 1. Alert your regional Perinatal HBV Denote the date and that the patient Coordinator. is not pregnant in the General 2. Open a 'Hepatitis B Positive Comments within the Case Info tab of Pregnant Female' NBS investigation. the 'Hepatitis B, acute' or 'Hepatitis B, 3. Fill in the data needed in the chronic' investigation. Patient, Case Info, and Hepatitis Core Example: '10/26/2016 - field tabs as indicated by pages 51-54 of investigated and patient found to not the User Guide. be pregnant.' 4. Close the NBS investigation and

*Although not preferred, in lieu of denoting pregnancy status in the General Comments of the HBV investigation, you may elect to open a 'Hepatitis B Positive Pregnant Female' NBS investigation and denote case status as 'Not a Case' for each pregnancy investigation.

denote case status as 'confirmed.'

Perinatal Hepatitis B NBS Investigations

Infants less than 24 months of age who were born in the United States to an HBV-positive mother or with laboratory evidence indicative of HBV infection are entered into NBS. Laboratory evidence of HBV infection in an infant consists of one or more of the following: positive HBsAg (only if at least 4 weeks after the last dose of HBV vaccine), positive HBeAg, and/or detectable HBV DNA.

The 2017 CDC/CSTE Case Definition can be found at: https://wwwn.cdc.gov/nndss/conditions/hepatitis-b-perinatal-virus-infection/case-definition/2017/

All infants born to HBV positive mothers are tracked in a separate (REDCap) database.

Please contact your Regional Perinatal HBV Coordinator or Janice Johnson at M.Janice.Johnson@tn.gov or 615-253-1359 with any questions you may have pertaining to perinatal HBV investigations.

Hepatitis C NBS Investigations

Acute HCV is reportable to the Health Department (HD).

In order to properly categorize cases of Hepatitis C infection, the HD and public health regions should take the following steps upon receipt of HCV lab reports, as well as clinical reports of suspected acute HCV:

1) <u>Lab Management of HCV Lab Reports in NBS</u> (performed by the Central Office)

- Electronic Laboratory Reports (ELR):
 - All HCV laboratory reports are to be associated with a client/investigation and have a case status determined.
- Manual/Paper Laboratory Reports:
 - All pertinent paper laboratory reports (positive and negative) that support a case status determination need to be entered into NBS as a laboratory report and associated with the investigation.

2) Field Investigations of HCV (performed by the Public Health Regions)

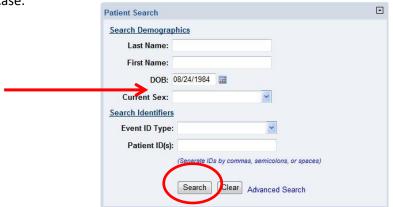
- All **suspected acute HCV** (clinician report, risk factors, associated labs) reported to regions will continue to be field investigated by the regions, regardless of the age of the patient.
 - For best practices, laboratory reports/results given over the phone should be supported by a paper laboratory report. If verbal laboratory results are given, please make every effort (via lab or provider) to obtain a paper copy of these results.
- All **other newly reported HCV cases** falling into groups at increased risk for acute HCV infection will be field investigated by Central Office.
 - Note: During the course of Central Office investigations (NBS or field), if any information suggests acute infection (elevated ALT, etc.), the investigation will be forwarded to the respective region for field investigation.
 - Standardized Tools Aiding in Field Investigations of Suspected Acute (Appendix B):
 Provider Requesting Records letter, HBV/HCV Case Report Form, a letter for
 contacts to an acute HBV or acute HCV case, Accurint Records Search Request Form,
 and Public Health Authority letter (if necessary)

Note: Detailed instructions for creating an NBS investigation, determining case status, and conducting field investigations for HCV are described below. For additional information pertaining to the provision of HCV testing in local health departments, you may access the HCV Testing Nursing Protocol, HCV Testing and Training Manual, Health Department Just-In Time Training, and the Specimen Collection and Transport Guidelines on SharePoint:

https://tennessee.sharepoint.com/sites/health/CEDEP/HSVH/Documents/Forms/Default.aspx?id=%2Fsites%2Fhealth%2FCEDEP%2FHSVH%2FDocuments%2FViral%20Hepatitis%2FTesting

1. To avoid creating duplicate patient records in NBS, search for the patient by looking up their Date of Birth (DOB), followed by the first common letters of the name (to account for multiple spellings of names, ex: Steven or Stephen you would search for 'Ste'):

a. When searching, names entered with all capital letters appear first, followed by those entered with both capital and lower case letters, followed by those entirely in lower case.

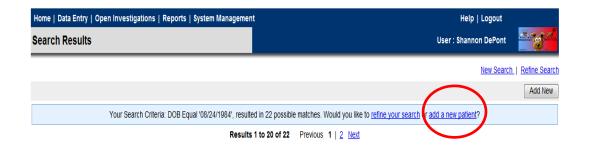


- i. If the patient has more than one NBS profile and needs to be merged, please send an email to Shannon.Depont@tn.gov with 'Merge Patient' in the Subject line and, in the email, include your DC# and the PSN/Patient ID. Shannon will determine if the patient meets the merging criteria.
 - 1. If there is an error in the name for one of the patient records, please correct the name before requesting the merge.
 - 2. Do not send any additional information about the patients, such as patient name or date of birth. If this information is required, please contact Shannon De Pont via telephone at 615-532-8518.
 - 3. When the NBS System Administrator merges the patient records, only one of the PSN numbers will be preserved and available when searching. Make note of all of the PSN numbers for the next step.

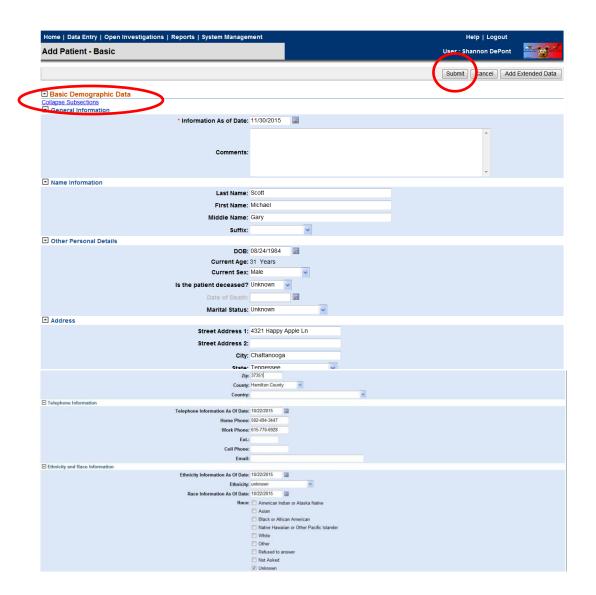
After the patient records are merged, you will need to make sure there are not duplicate lab reports or investigations. All of the lab reports and investigations for the merged patients will now be listed in a single patient record. Follow the steps for managing duplicate lab reports or investigations, and ensure the appropriate associations are made.

2. Before creating an investigation for an Electronic Laboratory Report (ELR), check NBS for the patient as you would when manually entering a paper laboratory report.

- a. If the patient is not in NBS, add them and their laboratory report(s) into NBS:
 - i. Click 'add a new patient':



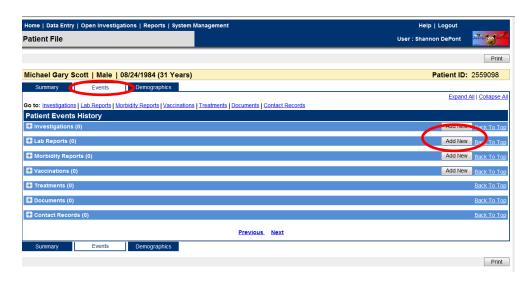
- ii. NBS will direct you to fill in the Basic Demographic Data with any known patient data:
 - 1. Fill out any information appearing on the laboratory report.
 - 2. <u>Unless otherwise specified on the lab, mark the subsequent fields as</u> follows:
 - a. Information As of Date: Auto populates
 - b. Comment: Skip/leave blank unless needed
 - c. Is the patient deceased?: Unknown
 - d. Marital Status: Unknown
 - e. Full Address
 - i. County: Does not auto populate, please research via the following resource:
 - https://tools.usps.com/go/ZipLookupAction input
 - ii. Census Tract: Skip/leave blank
 - f. Phone/email: (if known)
 - g. Ethnicity: Unknown
 - h. Race: Unknown
- iii. Do not enter information for type, assigning authority, or ID Value
- iv. Click Submit



b. If the patient is in NBS, click on their Patient ID:



3. To add a lab, click on the events tab, then Add New next to Lab Reports:

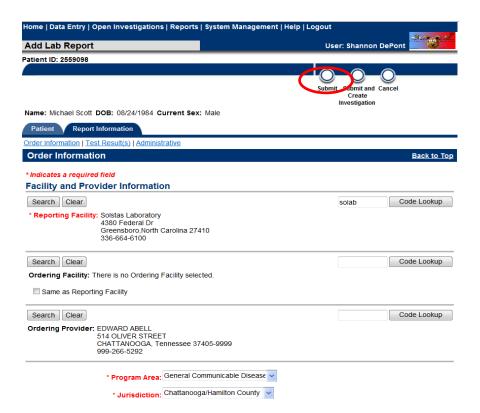


- a. When entering a lab (in a new jurisdiction) for an existing investigation (in a different jurisdiction), refer to step 13 on page 90 for guidance on transferring jurisdiction.
 - i. Mark the laboratory fields as indicated below:
 - Reporting Facility (if facility is not found, refer to appendix C for instruction on adding an organization)
 - 2. Ordering Facility: Only if listed on lab (if facility is not found, refer to appendix C for instruction on adding an organization)
 - 3. Ordering Provider (if provider is not found, refer to appendix C for instruction on adding a provider)
 - 4. Program Area: General Communicable Disease
 - 5. Jurisdiction (auto populates based on county you entered in the previous step)
 - 6. Lab Report Date: Use the lab's resulted/verified/completed/report date
 - 7. Date Received by Public Health: Date you received the lab
 - 8. Ordered Test
 - Refer to NBS Lab Translator sheet (Appendix C), fill in corresponding result, and click Select.
 - 9. Accession Number: If given
 - 10. Specimen Source: Serum, unless otherwise specified
 - 11. Specimen Site: Skip (leave blank)
 - 12. Date Specimen Collected: Collection Date
 - 13. Patient Status at Specimen Collection: Unknown, unless otherwise specified
 - 14. Pregnant:

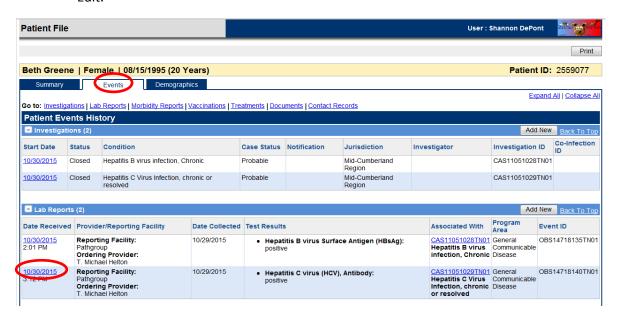
- a. Unknown: If patient is female and has unknown pregnancy status
- b. Pregnant: If patient is female and status is known to be pregnant
- c. Skip: If patient is male

15. Resulted test:

- a. Refer to NBS Lab Translator sheet (Appendix C)
- b. Fill in corresponding result
- c. Click Add Test Result
- 16. Click Submit



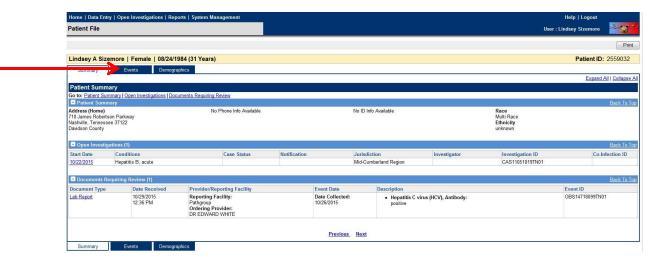
b. To edit a previously entered lab, click the events tab, and then the date received. Click Edit.







- i. If you receive both qualitative and quantitative results, please enter both results. However, if you receive both a numerical result and a log result for the same lab on the same date, please enter only the numerical result.
- ii. Click Submit.
- c. Prior to conducting your field investigation for newly reported HCV cases that are suspected of having acute HCV (clinician report, risk factors, associated labs), check to see if they have an existing HCV investigation by clicking on events:



For steps 1-4 below, please refer to the flow chart on page 71 for proper assignment of case status.

- 1. For those with an existing chronic HCV investigation:
 - Send the lab(s) to central office, attention Shannon De Pont (refer to Notes Regarding HCV Investigations section for address information).
- 2. For those with an existing acute HCV investigation:
 - a. If additional labs are received related to the acute hepatitis C condition, they should be associated with the existing hepatitis C acute investigation, even if the investigation has been closed, and case status should be updated, if necessary. A second investigation should not be created unless:
 - i. A positive/reactive lab report is received for another viral hepatitis infection (HBV, HAV)
 - Create an investigation for the additional viral hepatitis infection, acute or chronic, as appropriate.
 - ii. A positive lab report is received with collection date greater than <u>12 months</u> from the date of collection (in the existing HCV acute investigation)
 - Send the lab to central office, attention
 Shannon De Pont (refer to Notes Regarding HCV Investigations section for address information).
 - b. If there is documentation (either from the lab itself or from the physician follow-up) that the patient has been treated and achieved sustained virologic response and you receive additional positive HCV lab reports, create a new acute HCV investigation.
- 3. For those with existing acute <u>and</u> chronic HCV investigations:
 - a. Send the lab to central office, attention Shannon De Pont (refer to Notes Regarding HCV Investigations section for address information).
- 4. For those with multiple existing acute or multiple existing chronic HCV investigations:
 - a. Refer to the earliest investigation and update the case status (if necessary), associate all HCV labs with this investigation, and change the case status for the repetitive HCV chronic investigations to 'not a case.'

i. For example, if you have a chronic HCV investigation with an investigation start date of 6/17/2006 and another with an investigation start date of 9/30/2011, you will update the case status for the 6/17/2006 investigation (if necessary), associate all HCV labs to the 6/17/2006 investigation, and change the case status for the 9/30/2011 investigation to 'not a case.' This will ensure our case counts to CDC are correct.

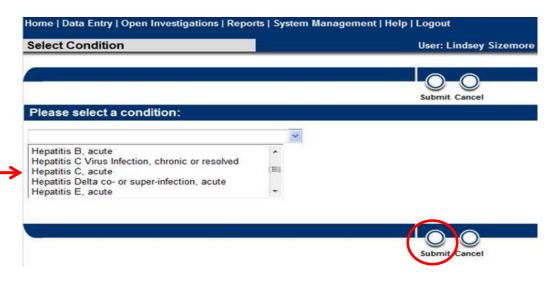
Acute HCV					12 Months After Onset of Acute HCV	Chronic HCV		
Case Status	Symptoms	Jaundice or ALT > 200 IU/L	HCV Ab(+)	NAT(+) or HCV Ag(+)	If receive additional lab results dated > 12 months of onset of acute HCV infection, open a chronic HCV investigation	Case Status	HCV Ab(+)	NAT(+) or HCV Ag(+)
Confirmed	٧	٧	(+/-)	٧		Confirmed	(+/-)	٧
						Probable		
Probable*	٧	٧	٧	x		Confirmed	(+/-)	٧
						Probable	٧	X

^{*} If receive positive HCV NATor positive HCV Ag results dated < 12 months of onset of "acute HCV, probable", reclassify as "acute HCV, confirmed".

4. To create a HCV investigation, click Add New:



a. <u>For condition, select acute, hepatitis C if you are preparing to do a field investigation.</u>
Otherwise, send the lab to central office, attention Shannon De Pont (refer to Notes Regarding HCV Investigations section for additional information).



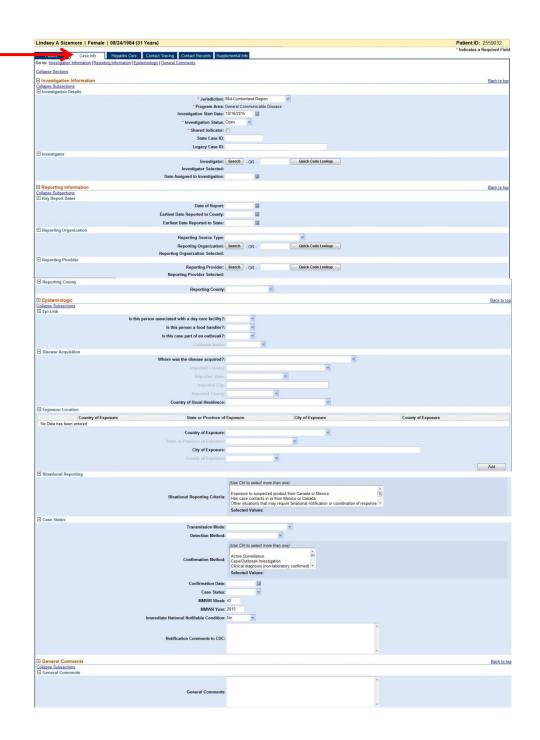
- i. In the prior NBS Hepatitis pages, you could only select "Hepatitis" as the condition and would modify the diagnosis within the investigation to reflect "hepatitis C, acute" or "hepatitis C, past or present" (chronic) prior to closing the investigation.
- ii. "Hepatitis" is still an option for condition; however, we request that you choose the specific condition ("hepatitis C, acute" or "hepatitis C, chronic") from the beginning.
- iii. The condition you choose from the beginning makes a difference in which extended tabs you will have access to.
 - 1. If the condition selected is acute, you are planning to conduct a field investigation, which includes sending out the provider requesting records letter (Appendix B).
 - 2. Once the provider requesting records letter is received back, you can use this information to fill out the case report form (Appendix B). This will be used to populate the NBS tabs discussed below.
- 5. Under the Patient tab, the following data is pre-populated based on the information within the patient's NBS record (assuming the information was present in patient's record):
 - a. If you are aware that any of the patient's information has changed, update it within the investigation. This will update the information within the NBS record to reflect the most

current information. More importantly, it will keep both the past and present information in the record for historical context.

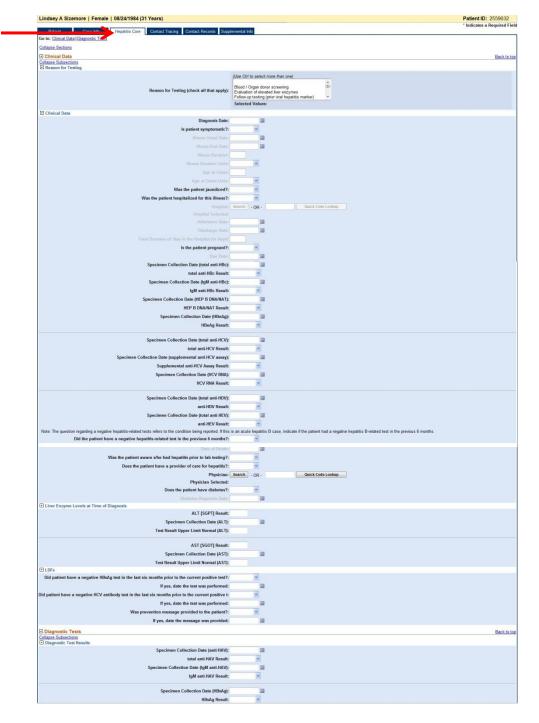
You should only update this information within the investigation under the
 Patient tab (see below). DO NOT update this information in the Demographics
 tab on the Patient home screen as this will impact the historical data within
 NBS.

Lindsey A Sizemore Female 08/24/1984 (31	Years)	Patient ID
Patient Case Info Hepatitis Core	Hepatitis Extended Contact Tracing Contact Records Supplemental Info	* Indicates
■ Patient Information		
Collapse Subsections General Information		
	* Information As of Date: 11/19/2015	
		^
	Comments:	
		-
■ Name Information		
	First Name: Lindsey	
	Middle Name: A Last Name: Sizemore	
	Suffix:	
■ Other Personal Details		
	Date of Birth: 08/24/1984	
	Reported Age Units: Years	
	Reported Age Units: Years Current Sex: Female	
	Country of Birth:	
	Is the patient deceased?: No	
	Deceased Date:	
Reporting Address for Case Counting	27 (ASS) V-0. (1910-2-1	
	Street Address 1: 710 James Robertson Parkway Street Address 2:	
	City: Nashville	
	State: Tennessee	
	Zip: 37122	
	County: Davidson County	
	Country: United States	
Telephone Information	Home Phone: 502-494-3447	
	Work Phone: 615-770-6928	
	Ext.:	
	Cell Phone:	
	Email:	
Ethnicity and Race Information	Ethnicity: unknown	
	Race: American Indian or Alaska Native	
	Asian	
	 Black or African American Native Hawaiian or Other Pacific Islander 	
	White	
	Other	
	Refused to answerNot Asked	
	✓ Unknown	
	Previous. Next	

- 6. Under the Case Info tab, the Jurisdiction, Program Area, Investigation Start Date, Investigation Status, MMWR Week, MMWR Year, and Immediate National Notifiable Condition are prepopulated based on the information within the patient's NBS record (assuming the information was present in patient's record) and are based on the date you open the investigation:
 - a. You will fill out the following information for surveillance purposes:
 - i. Date of Interview (if patient was interviewed)
 - ii. Reason why patient was not interviewed (if patient was not interviewed)
 - iii. Investigator (Search for yourself or enter your quick code)
 - iv. Date Assigned to Investigation use the date you were assigned the investigation
 - v. Reporting Source Type (the type of facility that reported the case), if known. If not known, leave blank.
 - vi. Is this case part of an outbreak?
 - 1. If yes, select the outbreak name (central office will assign an outbreak name if this occurs)
 - vii. Where was this disease acquired, if known? If not known, leave blank.
 - viii. Country of Usual Residence (if outside of the United States)
 - ix. Country of Exposure (if outside of the United States)
 - x. Detection Method
 - xi. Case Status 'suspect' can be selected initially while waiting to receive the provider requesting records letter back; however, it must be changed to reflect the appropriate case status (Appendix A) prior to closing the investigation.
 - xii. General Comments this is where you will put any additional information gathered from the field investigation that you feel are pertinent.
 - For example, if a patient indicates they share body jewelry, you would indicate that here as it isn't captured elsewhere in the NBS investigation.



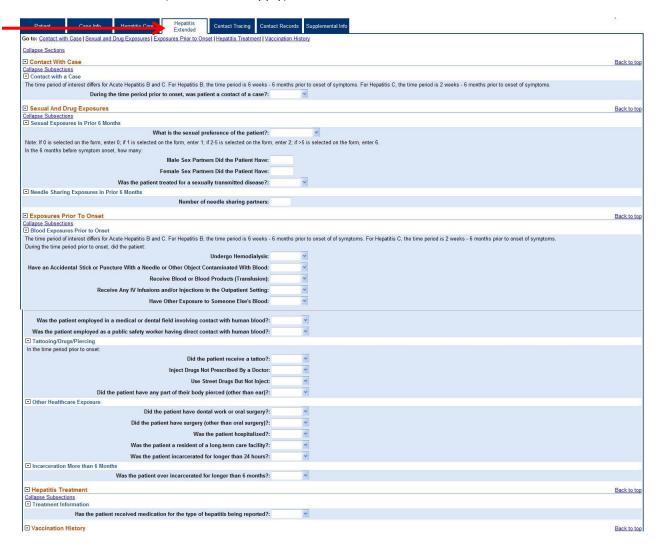
- 7. The Hepatitis Core tab appears within the investigation for all hepatitides.
 - a. Central Office will interpret those items with unknown selected to mean the patient was lost to follow-up or refused to answer.
 - b. Central Office will interpret those items with nothing selected (blank) to mean the case is still being worked up and the field investigation is not complete.
 - c. You will fill out the following information for surveillance purposes:
 - i. Reason for Testing (check all that apply)
 - ii. Diagnosis Date use the lab's resulted/verified/completed/report date (same as the resulted date when the lab is entered)
 - iii. Is patient symptomatic? If yes, and if known:
 - 1. Illness Onset Date
 - iv. Was the patient jaundiced?
 - v. Was the patient hospitalized for this illness? If yes, and if known:
 - 1. Hospital's information
 - 2. Admission Date
 - 3. Discharge Date
 - vi. Is the patient pregnant? If yes,
 - 1. Due Date
 - vii. Did the patient die from this illness? If yes, and if known:
 - 1. Date of Death
 - a. You must be certain the patient died from the hepatitis indicated as the investigation condition and not from another primary cause.
 - viii. Was the patient aware s/he had hepatitis prior to lab testing?
 - ix. Does the patient have a provider of care for hepatitis? If yes, and if known:
 - 1. Physician's information
 - x. Does the patient have diabetes? If yes, and if known:
 - 1. Diabetes diagnosis date
 - a. If you only know the year, please denote the appropriate year and use 01/01 for the month and day, respectively.
 - 2. If patient has diabetes, select all that apply
 - xi. Fill in any lab criteria that pertain to the labs you have entered (or were imported via ELR) that will be associated with this investigation. This should be completed for both positive and negative labs.
 - 1. For numeral xi section only, if there is information you do not know, you can leave the fields blank. You do not need to select Unknown.



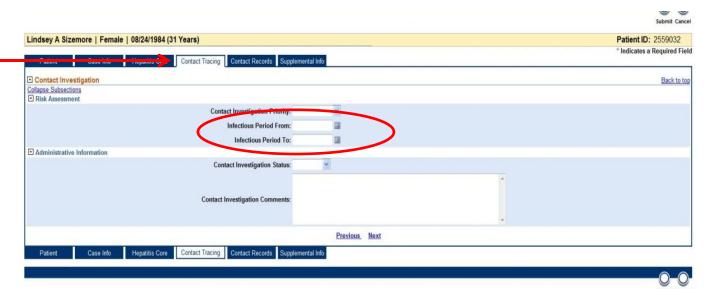
- 8. The Hepatitis Extended tab appears within the investigation and differs depending on what Hepatitis condition was selected when opening the investigation. All known fields in this tab must be filled out after conducting the "hepatitis C, acute" field investigation. If you determine after the field investigation that, based on the information you acquired, the patient meets the case definition for "hepatitis C, chronic" as opposed to "hepatitis C, acute", refer to step 16 on page 93 for how to change the condition to "hepatitis C, chronic".
 - a. Contact with a Case asks if the patient was aware that they were a contact to a known case of HCV. If you select yes, NBS asks for the type of contact the patient had with that

individual (sexual, needle, household, or other). If other is selected, please specify the type of contact in the text box.

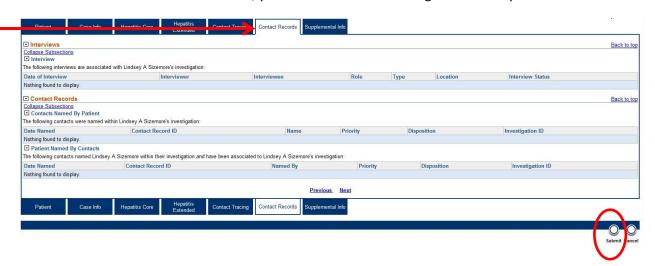
i. In the Hepatitis Extended tab, some fields will not populate unless yes is selected. For example, if you select Yes for "Did the patient receive a tattoo?" another set of questions will appear asking where the tattooing was performed (check all that apply).



- 9. Under the Contact Tracing tab, you are trying to determine who the patient could have exposed to HCV and contact tracing should be conducted on all acute HCV cases. You will fill out the following information for surveillance purposes:
 - a. Infectious Period From 2 weeks prior to the onset date
 - b. Infectious Period To 60 days after the onset date
 - i. Onset symptoms or, in absence of symptoms, the first positive lab
 - ii. http://www.timeanddate.com/date/dateadd.html
 - c. Contact Investigation Status (mark as open until all contacts have been interviewed) and then close.
 - d. Contact Investigation Comments this is where you will put any additional information gathered from the field investigation that you feel are pertinent.

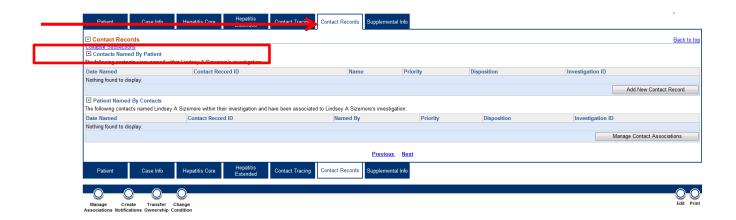


10. Under the Contact Records tab, you must submit the investigation before you can add a contact.



- a. Once you submit, select the contact records tab again. You will need to enter the following information for surveillance purposes:
 - i. Contacts Named by Patient: These are persons that the case you are investigating has named as contacts during their infectious period.
 - 1. You will need to add all named contacts.
 - ii. Patients Named by Contacts: These are persons that named the case you are investigating as a possible contact.
 - 1. Prepopulates from the record(s) of these contacts. If you are adding a new investigation, this field will be blank. You do not need to do anything with this field.

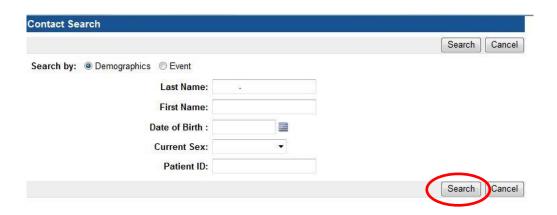
Remember: Always protect the confidentiality of the index patient's identity when interviewing contacts.



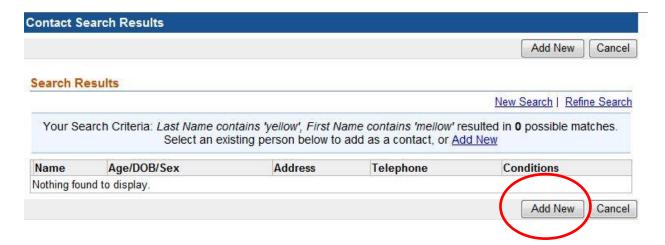
b. To add a new contact record, select Add New Contact Record:

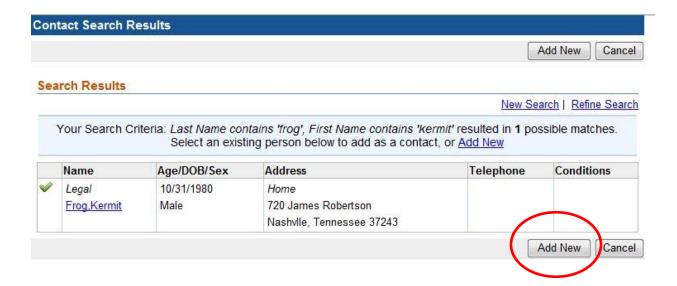


- c. To avoid creating duplicate patient records in NBS, search for the patient by looking up their Date of Birth (DOB), followed by the first common letters of the name (to account for multiple spellings of names, ex: Steven or Stephen you would search for 'Ste'):
 - Names entered with all capital letters appear first, followed by those entered with both capital and lower case letters, followed by those entirely in lower case.

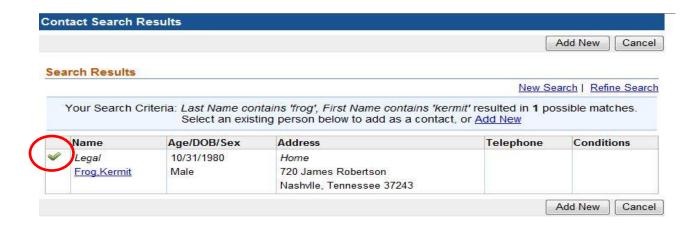


d. If the patient does not exist in NBS (or if you are not sure it is the same person), select Add New and add any known demographic information.

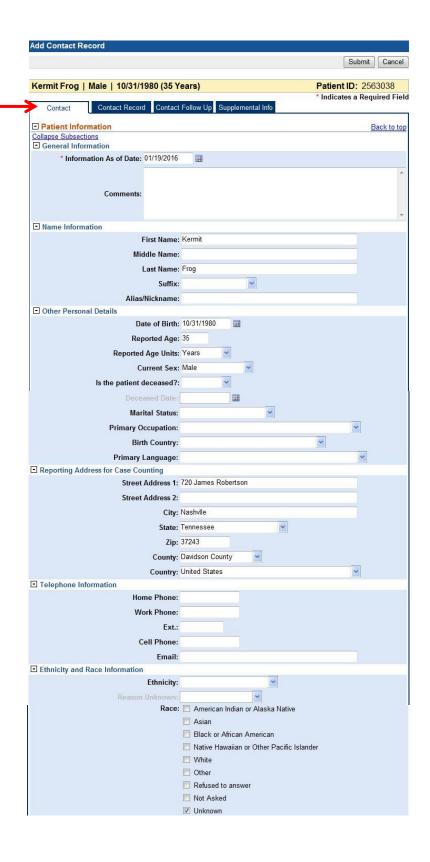




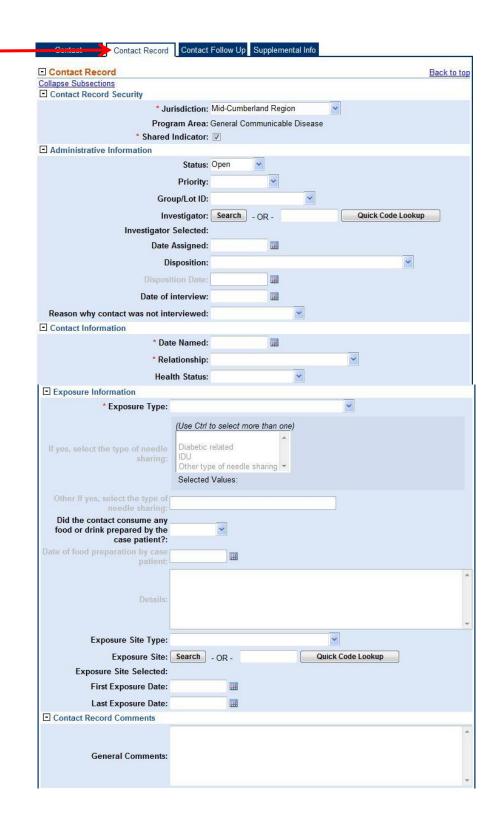
- e. If the patient is in NBS, select the green check mark next to their name
 - i. This will populate four additional tabs for the contact patient: Contact, Contact Record, Contact Follow Up, and Supplemental Info.



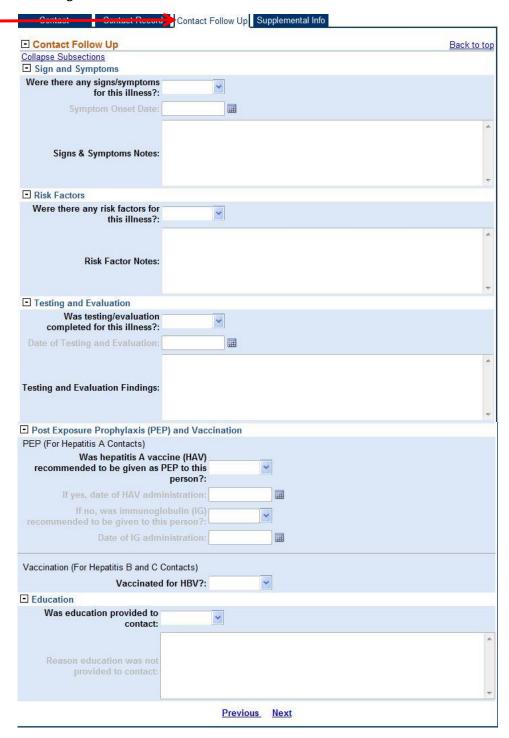
- f. Under the Contact tab, all patient information that exists in the NBS record will populate.
 - i. Update any information that has changed and/or any new information.
 - ii. Most of the information in the contact record cannot be filled out until you have interviewed the contact.
 - You can still add a contact record and reopen the record to add the information obtained from the interview. If you do this, be sure to change the 'Information as of Date.'



- g. Under the Contact Record tab, fill out the following:
 - i. Investigator (Search for yourself or enter your quick code)
 - ii. Disposition
 - iii. Date of Interview
 - iv. Reason why contact was not interviewed, if applicable
 - v. Date Named (date contact was named by index patient)
 - vi. Relationship
 - vii. Exposure Type
 - 1. If Other Needle Sharing type is selected, enter the type of needle sharing
 - viii. First Exposure Date, if known
 - ix. Last Exposure Date, if known
 - x. General Comments this is where you will put any additional information gathered from the field investigation that you feel are pertinent.



h. Under the Contact Follow Up tab, fill out any of the information you know after conducting the interview:



i. Under the Supplemental Info tab, you are not required to enter any information; however, you can use this as a place to upload the HBV/HCV Case Report Form or any other supporting documentation from your investigation.

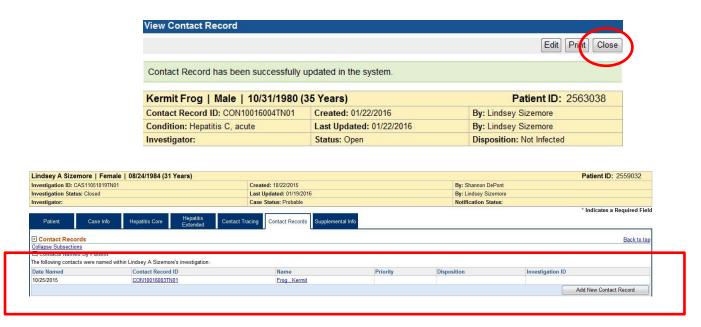


j. Once all tabs within the contact record have been filled out, click on the Contact Record tab, change the contact record status to closed, and click SUBMIT. This will save the contact record.

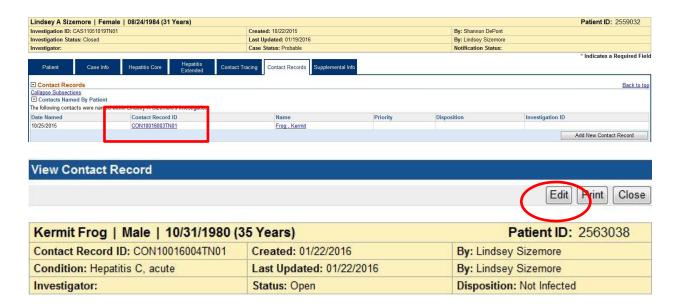


k. Select close to close the contact record. This record is now listed under the original patient as a contact.

I. To add additional contacts, follow the same steps as above.



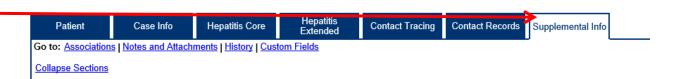
m. To edit or add additional information within a contact record, click on the Contact Record ID, click Edit, update the contact record information accordingly, and click Submit.



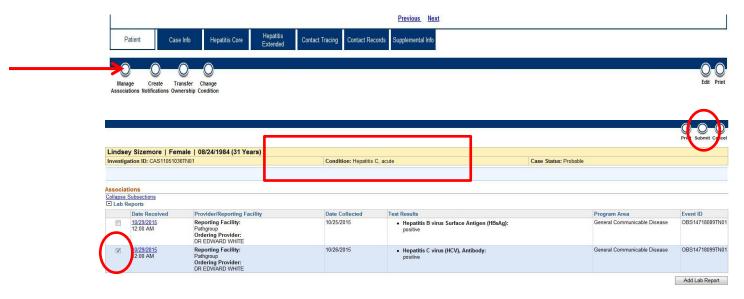
10. If you need to change information within an investigation, you can go back into the investigation, click Edit, update the Investigation information accordingly, and click SUBMIT.



11. Under the Supplemental Info tab, you are not required to enter any information; however, you can use this as a place to upload the HBV/HCV Case Report form or any other supporting documentation from your investigation.



12. Once the investigation has been submitted, click on Manage Associations to associate HCV laboratory reports (paper or electronic) to the investigation:



13. Guidance for Transferring Jurisdiction

Out of Tennessee Procedure

Out of Tennessee Paper Laboratory Reports

- Does the patient have an existing non-perinatal Hepatitis B or Hepatitis C NBS investigation?
 - If Yes
 - Transfer jurisdiction to Out of Tennessee, denote the appropriate state (and patient address) where the information will need to be transferred to on laboratory report, and send laboratory report to central office:

Tennessee Department of Health
Andrew Johnson Tower - HIV/STD/Viral Hepatitis Section – 4th Floor
Attention: Shannon De Pont
710 James Robertson Parkway
Nashville, TN 37243

- o If No
 - Send paper laboratory report to central office:

Tennessee Department of Health
Andrew Johnson Tower - HIV/STD/Viral Hepatitis Section – 4th Floor
Attention: Shannon De Pont
710 James Robertson Parkway
Nashville, TN 37243

Viral Hepatitis staff will coordinate with Surveillance Systems and Informatics Program (SSIP) to alert appropriate state.

Out of Tennessee Electronic Laboratory Reports (ELR)*

- Does the patient have an existing non-perinatal Hepatitis B or Hepatitis C NBS investigation?
 - o If Yes
 - The investigation status needs to be marked as Open, which allows the investigation to show in the Open Investigations Queue.
 - Associate any relevant laboratory reports with this investigation (ELR and any existing paper laboratory reports).
 - Select 'Edit' in the investigation and update the demographic information in the
 'Patient' tab to reflect the address for the other jurisdiction.
 - As a reminder, change the demographics within the investigation and NOT in the Demographics tab, as the demographics you enter in the investigation will transfer to the Demographics tab.
 - Select 'Transfer Ownership' and change the jurisdiction to Out of Tennessee.
 - The investigation will show in the Open Investigation Queue under the Out of Tennessee jurisdiction for the SSI program to send the investigation and associated labs on to the new state or territory. Once the investigation has been forwarded on, the SSI program will change the case status to Not a Case and the investigation status to Closed.

An email needs to be sent notifying the SSI program about the transfer only if the investigation status has been changed to Closed, because the investigation will not show in the Open Investigations Queue. Then, email CEDS.Informatics@tn.gov with the Investigation ID (CAS#).

o If No

- Select 'Edit' in the lab report.
- Update the patient address in the lab report.
 - For manual labs, the demographic information may be updated in the Patient tab.
 - For electronic lab reports, the address will need to be added as Add Comment under Lab Report Comments toward the bottom of the lab report.



- Select 'Transfer Ownership' and change the jurisdiction to Out of Tennessee
 - If the lab was <u>NOT</u> marked as reviewed, and you can still see the Mark
 as Reviewed button, the receiving Surveillance Systems and Informatics
 (SSI) Program at the Central Office will see the lab report in their
 'Documents Requiring Review' work queue to be able to send the report
 to the new state or territory.
 - If the lab was marked as reviewed, notify Surveillance Systems and Informatics Program (SSIP) by emailing the Patient ID Number/PSN to <u>CEDS.Informatics@tn.gov</u> and they will alert the respective state.
 - Note: This is only required for Hepatitis B ELR. Hepatitis C ELR will continue to be marked as reviewed and Central Office Viral Hepatitis staff will coordinate with the Surveillance Systems and Informatics Program to address these.

In-State Procedure

In-State Paper Laboratory Reports

In-State Investigations must be transferred to the jurisdiction listed on the most recent laboratory report received.

- Does the patient have an existing non-perinatal Hepatitis B or Hepatitis C NBS investigation?
 - o If Yes
 - Associate any relevant laboratory reports with this investigation (ELR and any existing paper laboratory reports)
 - Coordinate with the appropriate jurisdiction, using Patient ID, to:
 - Transfer the investigation

- Deliver paper laboratory reports not in NBS
- Update the address within the investigation to the new address, including the county
- o If No
 - Open an investigation following Viral Hepatitis investigation protocol
 - Coordinate with the appropriate jurisdiction to:
 - Deliver paper laboratory reports not in NBS

In-State Electronic Laboratory Reports (ELR)*

- Does the patient have an existing non-perinatal Hepatitis B or Hepatitis C NBS investigation?
 - o If Yes
 - Associate any relevant laboratory reports with this investigation (ELR and any existing paper laboratory reports)
 - Coordinate with the appropriate jurisdiction, using Patient ID, to:
 - Transfer the investigation
 - Update the address within the investigation to the new address, including the county
 - o If No
 - Open an investigation following Viral Hepatitis investigation protocol

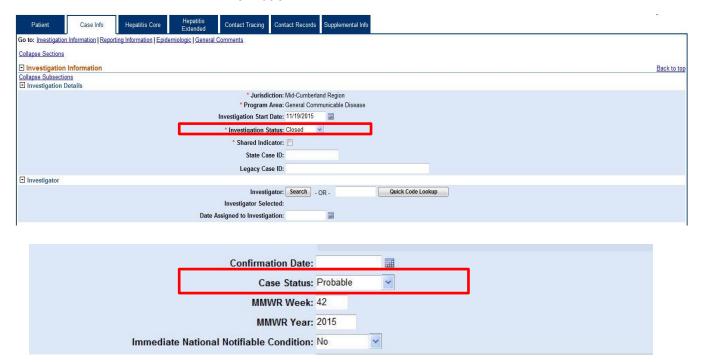
*Note: This is only required for Hepatitis B ELR. Hepatitis C ELR will continue to be marked as reviewed and Central Office Viral Hepatitis staff will coordinate with the Surveillance Systems and Informatics Program to address these.

The "ownership" of the investigation can be changed by clicking on Transfer Ownership at the top of the investigation and transferring the investigation to the correct jurisdiction.



- 14. Investigations must be closed within 30 days of the Investigation Start Date and a case status must be denoted.
 - a. To close the investigation, click on the Case Info tab and change the Investigation Status to "Closed."
 - b. To assign a case status per CDC/CSTE case definitions (Appendix A), click on the Case Info tab and select the appropriate case status.
 - i. <u>During the 30 days while the case is being worked up, a case status of 'Suspect' is appropriate as a placeholder; however, NO cases should be closed with a case status of 'Suspect.'</u>

- 1. Select the case status based on the information you have at 30 days.
- 2. The case status can be changed later should you acquire additional information.

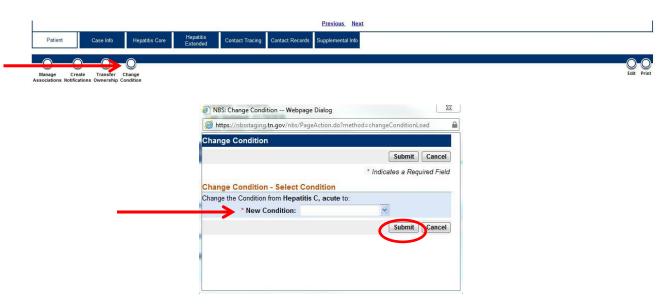


- 15. <u>A notification must be sent for each condition</u>. To do this, select Create Notifications and then select SUBMIT. Refer to Appendix D for more detailed guidance on the Case Notifications Procedure.
 - a. You should do this when you are closing the investigation to signal to Central Office that you are ready for the case to be reviewed.
 - i. <u>Do NOT create a notification for investigations with an Out of Tennessee</u> jurisdiction or with a case status of 'Not a Case.'
 - b. Any changes made to the investigation after the CDC notification has been sent will automatically be sent to CDC. There is no need to create another notification.
 - i. Any comments added in the notification comments will be transferred to CDC.

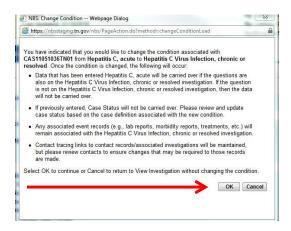




- 16. If after conducting the field investigation it is determined the patient was a case of "hepatitis C, chronic" instead of "hepatitis C, acute", select Change Condition, then the New Condition and SUBMIT.
 - a. This patient would <u>not</u> be "hepatitis C, acute" with a case status of 'Not a Case'; however, they would need to have their condition changed to "hepatitis C, chronic" with a case status of either 'Confirmed' or 'Probable.' <u>It is critically important to change</u> the condition and designate the appropriate case status for CDC reporting purposes.



b. When changing conditions, you will get the following warning message. This is letting you know that the previous condition selected will not carry over, any events (laboratory reports) you associated will remain associated, and any contact tracing links will be maintained. Most importantly, however, it is letting you know that any information currently under the "hepatitis C, acute" extended tab that is not also in the "hepatitis C, chronic" extended will not transfer over. Select OK.



c. The Hepatitis Extended tab will now be populated with the "hepatitis C, chronic" fields. You do not need to fill out the additional information related to the HCV chronic condition if you don't have it (i.e. you don't need to try to acquire it; however, if you have it, please enter it).



i. In a situation where you changed the condition from acute to chronic, under the Case Info tab, select 'Yes' for the question 'Was the patient assessed for acute disease and determined to not have acute disease?"



Notes Regarding HCV Investigations

With respect to HCV, patients should have no more than one investigation for an acute infection and one investigation for a chronic infection. Creating multiple investigations for acute or chronic affects cases count information reported to CDC.

HCV Electronic Laboratory Reports (ELR) not associated with an investigation can continue to be marked as reviewed; however, you will need to type the county name in the Lab Report Comments section before you mark it as reviewed.



This process will create orphan HCV laboratory reports; however, central office surveillance staff will address these. Additionally, often times ALT results are received via ELR and we understand that many will be orphaned in this process. If, when reviewing the orphan labs, we see an elevated ALT in addition to a positive anti-HCV and/or an HCV RNA, we will email the region on a case by case basis and ask them to conduct an acute HCV field investigation.

If you receive paper laboratory reports with more than one hepatitis test listed (i.e. a laboratory report with both HBV and HCV tests), please make a copy for yourself and mark out the HBV tests prior to sending the laboratory report to central office. Failure to do so may result in you receiving the HBV labs back, as central office administrative staff will not know the HBV labs have been entered.

If in doubt about whether or not to create an investigation or how to associate an ELR, please contact your Central Office Epidemiologist:

Lindsey Sizemore: lindsey.sizemore@tn.gov or 615-770-6928 (CHR, SER, SUL)

Jennifer Black: jennifer.black@tn.gov or 615-253-4782 (ETR, KKR, NER)

Travis Sondgerath: travis.sondgerath@tn.gov or 615-253-4452 (MCR, NDR, UCR)

Epidemiologist I - TBD (JMR, SCR, MSR, WTR)

If you need an Accurint search for a Hepatitis case, please fill out the form in Appendix B and send securely to Jennifer Black: jennifer.black@tn.gov

Please continue to send HCV laboratory reports that are not associated with suspected acute cases to Central Office, at the address below:

Tennessee Department of Health

Andrew Johnson Tower- HIV/STD/Viral Hepatitis Section – 4th Floor

Attention: Shannon De Pont

710 James Robertson Parkway

Nashville, TN 37243

Hepatitis D and Hepatitis E NBS Investigations

Hepatitis D and E are not reportable in the state of Tennessee; however, any lab reports containing Hepatitis D (HDV) or Hepatitis E (HEV) information must be sent to central office. Make a copy if the report contains any other laboratory reports you might need (HAV, HBV, HCV), and send to:

Tennessee Department of Health

Andrew Johnson Tower- HIV/STD/Viral Hepatitis Section – 4th Floor

Attention: Lindsey Sizemore

710 James Robertson Parkway

Nashville, TN 37243

For questions pertaining to HDV and HEV labs, please contact Lindsey Sizemore: lindsey.sizemore@tn.gov or 615-770-6928.

Appendix A: CDC/CSTE Case Definitions and NBS Case Status Classification

2012 CDC/CSTE HCV Case Definitions: Hepatitis B, acute

Clinical Description

An acute illness with a discrete onset of any sign or symptom* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain),

AND

a) jaundice

OR

 b) peak elevated serum alanine aminotransferase (ALT) level > 100 IU/L during the period of acute illness.

*A documented negative hepatitis B surface antigen (HBsAg) laboratory test result within 6 months prior to a positive test (either HBsAg, hepatitis B "e" antigen (HBeAg), or hepatitis B virus nucleic acid testing (HBV NAT), including genotype) result does not require acute clinical presentation to meet surveillance case definition.

Laboratory Criteria for Diagnosis

HBsAg positive **AND** Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done)

CDC Case Classification (Case Status)

Acute, confirmed: A case that meets clinical criteria, is laboratory confirmed, and is not known to have chronic hepatitis B.

Additional Tennessee Department of Health Case Classification (Case Status)

Acute, probable*: The following combination of tests:

Symptoms, or jaundice, or ALT >100, positive HBsAg, and unknown IgM anti-HBc

OR

Symptoms, or jaundice, or ALT>100, negative HBsAg, and positive IgM anti-HBc

ΩR

Regardless of symptoms, HBsAg positive, and IgM anti-HBc positive

OR

Regardless of symptoms, HBsAg positive, and unknown IgM anti-HBc

*Per internal Tennessee Department of Health discussions, if the patient has symptoms but no jaundice or elevated ALT, we will still classify them as acute, probable.

2012 CDC/CSTE HCV Case Definitions: Hepatitis B, chronic

Clinical Description

No symptoms are required. Persons with chronic hepatitis B virus (HBV) infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

Laboratory Criteria for Diagnosis

Immunoglobulin M (IgM) antibodies to hepatitis B core antigen (IgM anti-HBc) negative **AND** a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative and genotype testing) **OR**

HBsAg positive or nucleic acid test for HBV DNA positive (including qualitative, quantitative, and genotype testing) or HBeAg positive two times at least six months apart. (Any combination of these tests performed 6 months apart is acceptable).

Case Classification (Case Status)

Chronic, probable

A person with a single HBsAg positive or HBV DNA positive (including qualitative, quantitative, and genotype testing) or HBeAg positive lab result and does not meet the case definition for acute hepatitis B.

Chronic, confirmed

A person who meets either of the above laboratory criteria for diagnosis.

Comments

Multiple laboratory tests indicative of chronic HBV infection may be performed simultaneously on the same patient specimen as part of a "hepatitis panel." Testing performed in this manner may lead to seemingly discordant results, e.g., HBsAg-negative **AND** HBV DNA-positive. For the purposes of this case definition, any positive result among the three laboratory results mentioned above is acceptable, regardless of other testing results. Negative HBeAg results and HBV DNA levels below positive cutoff level do not confirm the absence of HBV infection.

HBV Case Status Classification Box and Applications of Case Status for HBV

Hepatitis B

	_	· · · · · · · · · · · · · · · · · · ·			
	I	II	III	IV	
	Symptomatic	☐ Jaundice and/or ALT >100	HBsAg (+)	☐ IgM anti-HBc (+)	
Acute, Confirmed:					
 Seroconversion: (-) HBsAg within 6mos prior to a (+) HBsAg, HBeAg/HBV NAT; OR All Boxes checked (I, II, III, and IV) OR Boxes I, II, and III checked with unknown IgM anti-HBc Acute, Probable: 					
 [Box I, and/or Box II], plus Box III checked with unknown IgM anti-HBc*; OR Boxes III and IV checked Chronic, Confirmed: 					
 (-) IgM anti-HBc and one (+) of the following: HBsAg, HBeAg, or HBV NAT; OR (+) HBsAg, HBeAg, HBV NAT two times ≥ 6 months apart (any combo) Chronic, Probable: 					
	 One (+) of the following: HBsAg, HBeAg, or HBV NAT 				

As highlighted in the footnote above, in order to assign appropriate condition (acute or chronic) and case status (probable or confirmed), it is critical to obtain the IgM anti-HBc result; negative IgM anti-HBc

is not synonymous with unknown IgM anti-HBc.

*While a (-) IgM anti-HBc would make this "Chronic, Confirmed", an absent IgM anti-HBc is not the same as a (-) IgM anti-HBc.

(-) or Unknown HBsAg, plus	Existing investigation in NBS (HAV or HCV)	
	Yes	No
(+) IgM anti- <u>HBc</u>	Associate labs with existing investigation	Create HBV investigation: Acute, not a case
(+) anti- <u>HBc</u>	Associate labs with existing investigation	Create HBV investigation: Chronic, not a case
(+) anti-HBs	Associate labs with existing investigation	Create HBV investigation: Chronic, not a case
(+) anti-HBe	Associate labs with existing investigation	Create HBV investigation: Chronic, not a case

Exception: If these labs are received on a **woman of reproductive age**, a field investigation will need to be conducted to determine pregnancy status and, if pregnant, acquire additional HBV labs for definitive case status determination.

While an investigation is being worked up, a case status of suspect can be used as a placeholder for the HBV conditions (acute or chronic) during this time.

All investigations must be closed within 30 days using the application of appropriate case status (confirmed, probable, or not a case). A case status of suspect does not fit within the CDC/CSTE case definitions as suspect is not an option.

Central office epidemiologists will be running monthly reports to check for those with an investigation start date that exceeds 30 days and for those with no investigation and will reach out to field staff directly if any of these are found.

2016 CDC/CSTE Case Definitions: Hepatitis C (acute and chronic)

Clinical Criteria

An illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain),

AND

a) jaundice

OR

b) peak elevated serum alanine aminotransferase (ALT) level > 200 IU/L during the period of acute illness.

Laboratory Criteria

A positive test for antibodies to hepatitis C virus (anti-HCV)

Hepatitis C virus detection test:

Nucleic acid test (NAT) for HCV RNA positive (including quantitative, qualitative or genotyping testing) or a positive test indicating the presence of hepatitis C viral antigen(s) (HCV antigen)*

Case Classification (Conditions and Case Status)

Acute, confirmed: A case that meets clinical criteria and has a positive hepatitis C virus detection test (HCV NAT or HCV antigen)

OR

A documented negative HCV antibody, HCV antigen or NAT laboratory test result followed within 12 months by a positive result of any of these tests (test conversion)

Acute, probable*: A case that meets clinical criteria and has a positive anti-HCV antibody test, but has no reports of a positive HCV NAT or positive HCV antigen tests

AND

Does not have test conversion within 12 months of has no report of test

*Per internal Tennessee Department of Health discussions, if the patient has symptoms but no jaundice or elevated ALT, we will still classify them as acute, probable.

Chronic, confirmed: A case that does not meet clinical criteria or has no report of clinical criteria **AND**

Does not have test conversion within 12 months or has no report of test conversion

AND

Has a positive HCV NAT or HCV antigen test

Chronic, probable: A case that does not meet clinical criteria or has no report of clinical criteria **AND**

Does not have test conversion within 12 months or has no report of test conversion

AND

Has a positive anti-HCV antibody test, but no report of a positive HCV NAT or positive HCV antigen test*

HCV Case Status Classification Box and Applications of Case Status for HCV

Hepatitis C

	Symptom(s) plus either		
	a) jaundice or b) ALT >200 IU/L		
	No or Unknown	Yes	
HCV Ab(+) only	Chronic,	Acute,	
	Probable —	Probable	
HCV NAT(+) or	Chronic,	Chronic,	
HCV Ag(+)	Confirmed —	Confirmed	

Acute

Seroconversion: (-) HCV Ab, HCV Ag, or HCV NAT followed by a (+) of any
of these within 12 months (see test conversion table below)= Acute,

Confirmed

Test Conversion within 12 Months Combinations

First Result	Second Result	
(-) HCV Ab	(+) HCV Ab, (+) HCV Ag or (+) HCV NAT	
(-) HCV Ag	(+) HCV Ag or (+) HCV NAT	
(-) HCV NAT	(+) HCV Ag or (+) HCV NAT	

Chronic:

- (+) HCV Ab, (-) RNA, and no other labs on file or the same results previously = Chronic, Probable
- (+) HCV Ab, (-) RNA, and prior (+) RNA = Chronic, Confirmed
- (-) HCV Ab, standalone = Chronic, Not a Case
- (-) HCV RNA, standalone = Chronic, Not a Case

While an investigation is being worked up, a case status of suspect can be used as a placeholder for the HCV acute condition.

All investigations must be closed within 30 days using the application of appropriate case status (confirmed, probable, or not a case). A case status of suspect does not fit within the CDC/CSTE case definitions as suspect is not an option.

Central office epidemiologists will be running monthly reports to check for those with an investigation start date that exceeds 30 days and for those with no investigation and will reach out to field staff directly if any of these are found.

Hepatitis B Testing and Counseling

GENERAL INFORMATION

Hepatitis B is a contagious liver disease that results from infection with the hepatitis B virus (HBV). It can range in severity from a mild illness lasting a few weeks to a serious, lifelong illness that damages the liver. Hepatitis B can be either "acute" or "chronic".

Acute hepatitis B infection is a short-term illness that can last a few weeks up to 6 months after exposure to HBV. Adults may or may not show symptoms, and children usually do not show symptoms. If present, symptoms typically appear 6 weeks to 6 months after exposure and may include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, or yellowing of the skin or eyes.

Chronic hepatitis B infection is a long-term illness that occurs when HBV remains in a person's body. Risk for chronic infection is age dependent: about 90% of infants infected with HBV infection at birth will develop chronic infection, while only about 5-10% of adults will develop long term infection. Chronic infection can last a lifetime and may lead to serious liver problems including cirrhosis (scarring of the liver), cancer, and liver failure leading to death.

The best way to prevent HBV infection is to be vaccinated. Hepatitis B is usually spread when blood, semen, or other body fluids from a person infected with HBV enters the body of someone who is not infected. This can happen during sexual contact, when sharing needles or other drug equipment, or from an infected mother to her baby during pregnancy or birth. It can also be transmitted from contact with objects that have even small amounts of infected blood on them (razors, toothbrushes, nail clippers, and medical devices) and unsanitary tattooing equipment. HBV can live outside the body and remain infectious for at least 7 days.

HBV screening begins with a blood test for the Hepatitis B Surface Antigen (HBsAg). A reactive or positive HBsAg test means that an individual is currently infected with HBV. Persons with a positive HBsAg can spread HBV to others regardless if they feel sick or well. Other markers of on-going infection include HBeAg and HBV DNA. Additional blood markers can provide information on whether a patient is immune to HBV based on prior vaccination or due to prior infection that has resolved. Please reference the attached information on interpreting Hepatitis B serology from the CDC. Interpreting some HBV results can be tricky, and individuals may need to be referred to their medical provider for additional follow-up/testing when test results are unclear or inconsistent.

WHO SHOULD BE TESTED

Testing is recommended for:

- Pregnant women (with each pregnancy)
- Individuals at high-risk for HBV infection, including:
 - o Children born to HBV infected mothers
 - Sexual contacts of HBV positive individuals
 - o History of injection drug use (even once)
 - o Household contacts of HBV positive individuals
 - o History of STD or multiple sex partners
 - Men who have sex with men
 - HIV positive individuals

- Occupational exposure
 History of long-term hemodialysis
 Persons born in or traveling to regions with intermediate or high rates of HBV

PROCEDURE

- Assess individual's risk status
- Determine need for testing and counseling
- If indicated, screen for HBsAg using currently available test and provide HBV counseling regarding:
 - Test results and instructions for follow-up testing (if indicated)
 - o Risk reduction
 - Additional recommended services

COUNSELING

• Test results

- ✓ If <u>HBsAg is negative</u>, the client is not currently infected with HBV
- ✓ If <u>HBsAg</u> is positive, the client has virus in the blood, can spread HBV to others, and needs referral and evaluation by a doctor experienced in diagnosing and treating HBV

Risk reduction counseling

- ✓ For all clients:
 - ➤ Do not share needles or other equipment to inject or snort drugs
 - ➤ Do not share other items that may come in contact with another person's blood (medical equipment or personal items)
 - ➤ Avoid unsanitary tattooing
 - > Use condoms consistently during all sexual activity
- ✓ Additionally, for HBV positive clients:
 - ➤ See a doctor regularly
 - Avoid alcohol, acetaminophen (Tylenol), or products containing acetaminophen, as they can damage the liver
 - Consult a health professional before taking any prescription or overthe-counter medications

o Additional recommended services

- ✓ Evaluation of immunization status (including Hepatitis A and Hepatitis B) and provision of indicated vaccines
- ✓ Testing/counseling for Hepatitis C
- ✓ Testing/counseling for other STDs (gonorrhea, chlamydia, syphilis, HIV)
- ✓ Preconception counseling and/or contraception to reduce the risk of unintended pregnancy and/or mother-to-child transmission

REFERENCES

- Centers for Disease Control and Prevention web page for Interpretation of Hepatitis B Serologic Test Results, http://www.cdc.gov/hepatitis/hbv/pdfs/serologicchartv8.pdf
- Centers for Disease Control and Prevention: Recommendations for Routine Testing and Follow-up for Chronic HBV Infection, 2008, http://www.cdc.gov/hepatitis/hbv/PDFs/ChronicHepBTestingFlwUp.pdf
- http://www.cdc.gov/nepatitis/nov/1 DFs/ChrometrepBTestingFTwOp.pdr
- Viral Hepatitis B information http://www.cdc.gov/hepatitis/hbv/index.htm
 Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th edition
- http://www.cdc.gov/vaccines/pubs/pinkbook/hepb.html
 - World Health Organization web page for Hepatitis B, http://www.who.int/csr/disease/hepatitis/whocdscsrlyo20022/en/index1.html
- Centers for Disease Control and Prevention web page for the ABCs of Hepatitis, http://www.cdc.gov/hepatitis/Resources/Professionals/PDFs/ABCTable.pdf

Hepatitis C Testing and Counseling

GENERAL INFORMATION

Hepatitis C is a contagious liver disease that results from infection with the hepatitis C virus (HCV). It can range in severity from a mild illness lasting a few weeks to a serious, lifelong illness that damages the liver. Hepatitis C can be either "acute" or "chronic".

Acute hepatitis C infection is a short-term illness that occurs within the first 12 months after someone is exposed to HCV. Approximately 75-85% of people who become infected with HCV develop chronic infection; the remaining 15-25% "clear" the virus on their own without treatment and do not develop chronic infection. Chronic hepatitis C infection is a long-term illness that occurs when HCV remains in a person's body. Chronic infection can last a lifetime and, over time, can lead to serious liver problems including cirrhosis and liver failure.

Hepatitis C is usually spread when blood from a person infected with HCV enters the body of someone who is not infected. Today, most people become infected with HCV by sharing needles or other equipment to inject drugs. HCV can also be transmitted from unsanitary tattooing equipment, contact with objects that have even small amounts of infected blood on them (snorting straws, medical equipment, personal items), unprotected sex, or blood transfusion or organ transplant prior to 1992.

Hepatitis C screening begins with an antibody test. A reactive or positive antibody test means that an individual has been infected with the HCV at some point in time, and a second HCV test (an HCV RNA test) is needed to see if the person is chronically infected.

WHO SHOULD BE TESTED

Testing is recommended for all persons:

- Born from 1945 through 1965, or
- At high-risk for HCV infection, including:
 - o History of injection drug use (even once)
 - History of illicit intranasal drug use (even once)
 - History of unregulated tattoo
 - History of incarceration
 - o HIV positive individual
 - o History of STD or multiple sex partners
 - o Sexual contact with HCV positive individual
 - o History of long-term hemodialysis
 - o Received a blood transfusion or organ transplant prior to 1992
 - Occupational exposure
 - o Child born to HCV infected mother

PROCEDURE

- Assess client's individual risk status
- Determine client's needs (testing, level of counseling)
- Screen for HCV using currently available test
- Provide HCV counseling regarding:
 - Test results and instructions for follow-up testing (if indicated)
 - Risk reduction
 - Additional recommended services

COUNSELING

- Test results
 - ✓ If HCV <u>antibody negative</u>, the client is not currently infected with HCV
 - For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA may be considered
 - ✓ IF HCV antibody positive, the client needs a follow-up test (HCV RNA)
 - ➤ If HCV RNA is negative, the client has cleared the infection and is NOT chronically infected; however, client is vulnerable to reinfection
 - ➤ If HCV RNA is positive, the client has virus in the blood and needs referral to and evaluation by a doctor experienced in diagnosing and treating Hepatitis C
- o Risk reduction counseling
 - ✓ For all clients:
 - > Do not share any needles or other equipment to inject or snort drugs
 - ➤ Avoid unsanitary tattooing
 - ➤ Do not share any other items that may come in contact with another person's blood (medical equipment, razors, toothbrushes, or other personal items)
 - Use condoms consistently during all sexual activity
 - ✓ For HCV positive clients
 - > See a doctor regularly
 - > Avoid alcohol
 - Consult a health professional before taking any prescription or overthe-counter medications, as they can damage the liver

Additional recommended services

- ✓ Testing/counseling for other STDs (gonorrhea, chlamydia, syphilis, HIV)
- ✓ Evaluation of immunization status (including Hepatitis A and Hepatitis B) and provision of indicated vaccines
- ✓ Preconception counseling and/or contraception to reduce the risk of unintended pregnancy and/or mother-to-child transmission

REFERENCES

- Centers for Disease Control and Prevention web page for Hepatitis C Information for the Public, http://www.cdc.gov/hepatitis/C/PatientEduC.htm.
- Centers for Disease Control "Hepatitis C: General Information", 2015, http://www.cdc.gov/hepatitis/HCV/PDFs/HepCGeneralFactSheet.pdf.
- Centers for Disease Control "Hepatitis C: What to Expect When Getting Tested", 2013, http://www.cdc.gov/hepatitis/HCV/PDFs/HepCGettingTested.pdf.

Appendix B: Standardized Statewide Tools

Case Report Form

Harafffin Board, Country Broad Form	
Hepatitis B or C - Case Report Form	
INVESTIGATION: Investigation start date:// Investigator name: Date of 1st Attempt:// PhoneLetter Date of 2nd Date of Interview:// Reason not Interviewed: Unable	d Attempt:/
Last: First: If Pediatric Case, Parent/Guardian Name:	Middle:
	County: Homeless
Employer: Occupation/Set	-
DEMOGRAPHIC INFORMATION	CLINICAL & DIAGNOSTIC DATA
Date of Birth:// Age: Provider N	Name, Address, and Phone:
Sender: Female Male Other: Ethnicity: Hispanic Non-Hispanic Other/Unknown Race: Black/African American American American American Indian/Alaska Native Yes No Asian Native Hawailan/Pacific Islander White Unknown Race Other Race, specify: Pos Neg Unk Name: Date of collection: / Pos Neg Unk Date of collection: A. Total anti-HAV Date of collection: ALT (SGP HBeAg HBV NAT (qual, quant Geno) Sympt Screen Screen Screen Screen Canti-HCV HCV NAT (qual, quant, Geno) Geno Ge	Unk Symptoms? (fever, headache, malaise, anorexia, n/v, diarrhea, abdominal pain) Jaundiced? Hospitalized for hepatitis? If YES, specify: Pregnant? If YES, due date: MEZYME LEVELS AT TIME OF DIAGNOSIS: PT) Result: AST (SGOT) Result: FOR TESTING: (check all that apply) oms of acute hepatitis ning of asymptomatic patient with reported risk factors in a screening station of elevated liver enzymes Organ donor screening -up testing for previous marker of viral hepatitis win
	specify:
CASE CLASSIFICATIO Hepatitis B	N.
I II IV	Hepatitis C
Symptomatic Jaundice and/or ALT > 100 HBsAg (+) IgM anti-HBs Acute, Confirmed:	Symptom(s) <u>plus</u> either a) joundice or b) ALT >200 IU/L
Seroconversion: (-) HBsAg within 6mos prior to a (+) HBsAg, HBeAg/HBV NA All Boyes charled (I. II. III. and IV) OR	T; OR No or unknown Yes
All Boxes checked (I, II, III, and IV) OR Boxes I, II, and III checked with unknown IgM anti-HBc Acute, Probable:	HCV Ab(+) only Chronic, Chronic, Probable Chronic
[Box I, and/or Box II], plus Box III checked with unknown IgM anti-HBc*; OR Boxes III and IV checked	HCV NAT(+) or Chronic, Acute, Confirmed Confirmed Confirmed
Chronic, Confirmed: • (-) IgM anti-HBc and one (+) of the following: HBsAg, HBeAg, or HBV NAT; OR • (+) HBsAg, HBeAg, HBV NAT two times 2 6 months apart (any combo) Chronic, Probable: • One (+) of the following: HBsAg, HBeAg, or HBV NAT	Acute, Confirmed: • Seroconversion: (-) HCV Ab, HCV Ag, or HCV NAT followed by a (+) of any of these within 12 months 1
PH-4296 Rev. 7/31/17	RDA 150

PATIENT HISTORY - ACUTE HEPATITIS B ONLY	CASE NAME:
INFECTION	TIMELINE
Enter onset date in heavy box. Count forwards and backwards to d	· · · · · · · · · · · · · · · · · · ·
about exposures between those dates. For Hepazizis B, expo (onset-symptoms or, in the absence of symptoms, first positive is	
about 60 days after onset of symptoms for most adults and independent of the control of the	
	EXPOSURE PERIOD COMMUNICABLE
6 months 3 months Time from onset: prior to onset prior to onset	6 weeks 60 days prior to onset ONSET after onset
Time from onset. prior to onset. prior to onset.	prior to oriset
Calendar dates:	· · · □ · □ □
Items in Italics are interviewer instructions; Items in bold indicate so	cript prompts:
POSSIBLE SOURCE(S) OF INFECT	TION DURING EXPOSURE PERIOD
First, I would like to ask you a few questions about exposure	
before the onset of illness. I will need to ask you questions ab	-
tattoos, piercings, and potential drug use. (Remind patient of da In the 6 months to 6 weeks before your onset of Illness:	te range conected from timeline.)
Yes No Unk	Yes No Unk
☐ ☐Were you: A contact of a person with	Did you: Receive a tattoo?
Hepatitis B? If YES, type of contact:	If YES, where was it performed? Commercial/Parior
Sexual	Correctional facility
☐ Needle ☐ Household (non-sexual)	☐ Self
Other:	Guiler Receive any body plercing (other than ear)?
Diabetic?	If YES, where was it performed?
Diabetes Diagnosis Date: If YES, (check all the apply)	☐ Commercial/Parlor ☐ Correctional Facility
☐ Use a blood glucose monitor	Self
Share a blood glucose monitor Inject insulin	Other Did you: Have dental work or oral surgery?
Share syringes or needles	☐ ☐ ☐ Did you: Have dental work or oral surgery? ☐ ☐ ☐ Have any other surgery (other than oral)?
Did you: Undergo hemodialysis?	☐ ☐Were you: Hospitalized?
Have an accidental stick or puncture with a needle or other object contaminated with blood?	If YES, name of Hospital:
Receive blood or blood products (transfusion)?	☐ ☐ ☐Incarcerated for longer than 24 hours?
If YES, when?// Receive any IV infusions or injections in the	If YES, what type of facility? ☐ Prison
outpatient setting?	Jall
☐ ☐ ☐Have other exposure to someone else's blood?	Juvenile Facility
Specify: Were you: Employed in a medical or dental	Did you: Inject drugs not prescribed by a doctor?
fleid involving direct contact with human blood?	□ □Use street drugs but not inject?
If YES, frequency of direct blood contact: Frequent (several times weekly)	Have any sexual contact? If YES, number of Male sexual partners?
☐ Infrequent (Several times weekly)	0 1 2-5 >5 Unit
Employed as a public safety worker (fire,	If YES, number of Female sexual partners?
police, corrections) involving direct contact with human blood?	0 1 2-5 >5 Unik
If YES, frequency of direct contact:	During your lifetime, were you EVER:
Frequent (several times weekly)	Treated for sexually transmitted diseases?
☐ Infrequent	If YES, year of most recent treatment: If YES, year of most recent treatment: Incarcerated for longer than 6 months?
	If YES, year incarceration completed?
	For how many months?2
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PATIENT HISTORY -	ACUTE HEPATITIS	C ONLY	CASE	NAME: _			
		INFECTION '	TIMELIN	E			
Ask about exposures b	eavy box. Count forwards a etween those dates. For He e absence of symptoms, firs	patitis C, expos	sure perio	d is 6 mo	nths to 2	weeks pr	lor to onset on-
Time from onset:	6 months prior to onset	3 months prior to onset	(POSURI		COMIMU weeks to onset	ONSET	60 days after onset
Calendar dates:		' _	•	•	<u> </u>	O	
Items in Italics are Interv	lewer Instructions; Items In I						
your onset of illness. tattoos, piercings, and	POSSISLE SOURCE k you a few questions abo I will need to ask you q potential drug use. (Remii	ut exposures y uestions about nd patient of date	ou may t various	ave had in Items, inc	the 6 mont luding socia	h to 2 wee	•
In the 6 months to 2 we Yes No Unk	eeks before your onset of	Illness:	Yes N	o Unk			
		with			d you: Recei YES, where w Commercial/ Correctional Self Other:	vas it performe Parior facility	ed?
If YES ☐ Use					_	as it performe Parior	her than ear)? d?
inje	ect Insulin are syringes or needles u: Undergo hemodialysis? in accidental stick or punctur or other object contaminated e blood or blood products (t	re with a I with blood?		If YES	Id you: Have ave any other lere you: Ho S, name of Ho resident of a	surgery (othe spitalized?	e facility?
If YES, Receive	when?// e any IV infusions or injection ent setting? ther exposure to someone e	ns in the		If YES	i, what type of Prison Jail	facility?	4 flouis :
Specify		noe o blood:		D	Juvenile Fac Id you: Inject	t drugs not pre	escribed by a doctor?
Involvir If YES, Intro I	ou: Employed in a medical ing direct contact with human , frequency of direct blood or quent (several times weekly equent yed as a public safety worke lons) involving direct contac	n blood? ontact:) r (fire, police,		u	se street drug ave any sexus YES, number 0 1 [s but not injectal contact? r of Male sexu	t? al partners? 5 Unk le sexual partners?
Fre	, frequency of direct contact quent (several times weekly equent			If YES	eated for sexi 3, year of most carcerated for 5, year incarce	ne, were you is ually transmitt to recent treatre in longer than 6 tration comple y months?	ed diseases? nent: i months? ted?
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	d before your illness onset (onset-symptoms or, in the absence of of date range collected from timeline.) I assure you that your
ONTACTS:	CONTACT FOLLOW-UP: (to be completed after interview)
Name: Gender: Female Male Age: Relation to case: (check all that apply) Household Sexual Needle sharing Tattoo equipment sharing Other, specify: Date of last exposure to contact: // Address: State: Phone number: { }	1. Name: Date of 1st attempt:/ Date of 2nd attempt:/ Date of interview:/ Reason not interviewed: Unable to contact Refused Date of birth:/ Occupation: Check all that apply: Symptomatic, onset date:/ Asymptomatic Tested positive Tested negative Not tested Not vaccinated Not vaccinated None, reason:
Name: Gender: Female Male Age: Relation to case: (check all that apply) Household Sexual Needle sharing Tattoo equipment sharing Other, specify: Date of last exposure to contact: / / / Address: State: Phone number: ()	2. Name: Date of 1st attempt://_ Date of 2nd attempt:/_/_ Date of interview:/_/_ Reason not interviewed: Unable to contact Refused
. Name:	3. Name: Date of 1st attempt:// Date of 2nd attempt: _/ / _ Date of interview: _/ /_ Reason not interviewed: Unable to contact Refused Date of birth: _/ / Occupation: Check all that apply: Symptomatic, onset date: _/ / Asymptomatic Tested positive Tested negative Not tested Not vaccinated Not vaccinated None, reason:
. Name:	4. Name: Date of 1st attempt:/ _/ Date of 2nd attempt:/ _/ Date of Interview:/ _/ Reason not Interviewed: Unable to contact Refused Date of birth:/ _/ Occupation: Check all that apply: Symptomatic, onset date:/ _/ Asymptomatic Tested positive Tested negative Not tested Vaccinated Not vaccinated Education provided: Yes None, reason:

Yes No	Did pat	EDUCATION AND lent complete 3-shot Hepatitis B	vaccine series?		
	If YES		_/	Provider/Phone	Verified Yes No
			<u> </u>		Yes No Yes No
	☐ Yes	Hepatitis B vaccination recomme s, recommended	nded?		
	☐ No,	specify reason: is A vaccination recommended?	-		
	ls patie		linator (see publ	ic health action list below).	
		Is less than 2 years old, was Hep		-	imission?
	If YES	, Mother's name: lent donate blood products, organ			
	If YES	, Date:/ Loc ducation provided on? (Check a)	ation:	g ore and sement	
	☐ Tes	ted for HIV		ofootod? (Industrian assaura	raman\
	☐ Mea	donating blood products, organs asures to avoid transmission		meded? (including ova and	semen)
	For	idance of liver toxins (e.g., alcoho females, counseling on need for	follow-up on any		
	Pos	healthcare workers, counseling of sibility of chronic infection from a			
		ducation provided? , specify:			
(Check all	I that apply)	PUBLIC	HEALTH ACTIO	NS	
Proph	ylaxis (HBIG) of a	ppropriate contacts recommende	d Contac	ct management follow-up cor	mpleted
□ Nur Vaccin	mber recommend nation of appropri	ed prophylaxis: ate contacts recommended	Pregna	ant patient referred to Perina	tal Coordinator
		ed vaccination:	Est	timated Date of Delivery: rinatal Case Number:	
		NOTE	S & COMMENTS	3	

Provider Records Request Letter

TN Department of Health	
Your Health Department Address: Your Name: Your Phone Number and Your Fax Number: Your Email:	
Name of Provider Address City, TN Zip Today's Date	
The Health Department has been notified by your lab of a positive hepatitis test for the following patient:	
Patient: DOB:	
Test result(s) received (tick all that apply): HBV Hepatitis B surface antigen (HBsAg) IgM antibody to hepatitis B core antigen (IgM anti-HBc)	
Other (specify): HCV	
Acute hepatitis B and acute hepatitis C are diseases that are reportable under the Tennessee Department of Health Notifiable Disease List as defined by CDC. [Tennessee Provider Reportable Diseases, 2017: https://apps health.tn.gov/ReportableDiseases/Common/2017 List For Healthcare Providers.pdf Tennessee Laboratory Reportable Diseases, 2017: https://apps health.tn.gov/ReportableDiseases/Common/2017 List For Laboratories.pdf	
We are requesting further information in order to define this illness as either acute, chronic, or not a case. Does this patient have a history of Hepatitis B or Hepatitis C? (tick all that apply) Yes, Hepatitis B; If so, chronic or acute (specify): Yes, Hepatitis C; If so, chronic or acute (specify):	
What is the pregnancy status on this individual? Pregnant; Estimated Due Date: Not Pregnant	
Additionally, we are requesting the following medical record(s) and/or lab report(s) (tick all that apply): Hospital History and Physical (if applicable)	
If the patient has acute hepatitis, we will contact the patient to obtain information about risk factors. Please email or fax this form and the requested information to the email or fax number at the top of this page. Thank you very much for your assistance in completing this case investigation.	
Sincerely,	
Your Name / Title	

Provider Records Request Letter for HBV Positive Females of Reproductive Age

	Your Health Department Address: Your Name:
Ye	our Phone Number and Your Fax Number:
	Your Email:
Name of Provider	
Address City, TN Zip	Today's Date
The Health Department has been notifie woman of reproductive age (11-50) with	ed by your lab of a positive test for Hepatitis B surface antigen (HBsAg) on h a known history of hepatitis B.
	llows up with each positive HBs Ag lab to determine the patient's pregnan: is required and positive labs are reportable under the Tennessee Departme ined by CDC.
Tennessee Provider Reportable Disease	
https://apps.health.tn.gov/ReportableDis	seases/Common/2017 List For Healthcare Providers.pdf
Tennessee Laboratory Reportable Disea	ases, 2017:
https://apps.health.tn.gov/ReportableDis	seases/Common/2017 List For Laboratories.pdf
We are requesting further information	n in order to establish pregnancy status of your patient.
are neednesting tortue, intolination	
	DOR:
Patient: Date of Lab(s):	DOB:
Patient: Date of Lab(s):	
Patient: Date of Lab(s): What is the pregnancy status on this ind	iividual?
Patient: Date of Lab(s): What is the pregnancy status on this ind	
Patient: Date of Lab(s): What is the pregnancy status on this ind Pregnant; Estimated D Not Pregnant	tividual? Due Date:
Patient: Date of Lab(s): What is the pregnancy status on this ind Pregnant; Estimated D Not Pregnant If the patient is determined to be pregna	tividual? Due Date:
Patient: Date of Lab(s): What is the pregnancy status on this ind Pregnant; Estimated D Not Pregnant If the patient is determined to be pregna in your region for case management, and	lividual? Due Date: unt, we will forward this information to the public health mursing coordinate d s/he may reach out to you for additional information.
Patient: Date of Lab(s): What is the pregnancy status on this ind Pregnant; Estimated D Not Pregnant If the patient is determined to be pregna in your region for case management, and	lividual? Due Date: unt, we will forward this information to the public health mursing coordinate
Patient: Date of Lab(s): What is the pregnancy status on this ind Pregnant; Estimated D Not Pregnant If the patient is determined to be pregna in your region for case management, and	tividual? Oue Date: unt, we will forward this information to the public health mussing coordinate d s/he may reach out to you for additional information. m to the email or fax number at the top of this page.
Patient: Date of Lab(s): What is the pregnancy status on this ind Pregnant; Estimated D Not Pregnant If the patient is determined to be pregna in your region for case management, and Please email or fax this completed for	bividual? Oue Date: int, we will forward this information to the public health mursing coordinate ds/he may reach out to you for additional information. m to the email or fax number at the top of this page.
Patient: Date of Lab(s): What is the pregnancy status on this ind Pregnant; Estimated D Not Pregnant If the patient is determined to be pregna in your region for case management, and Please email or fax this completed for Thank you very much for your assistance	tividual? Oue Date: unt, we will forward this information to the public health mussing coordinate d s/he may reach out to you for additional information. m to the email or fax number at the top of this page.

Letter for Contacts to Acute HBV or Acute HCV Cases



Your Health Department Address
Your Name:
Your Phone Number and Your Fax Number:
Your Email:

Name of Person Address City, TN Zip

Today's Date

This letter is to notify you of either a possible exposure to hepatitis or infection with hepatitis virus. Hepatitis virus infects the liver and if not managed properly, can lead to other medical complications such as liver failure, liver cancer, or even death. Infected persons can develop long term infections and unknowingly spread it to others.

Early signs and symptoms of infection include: abdominal pain, fever, fatigue, loss of appetite, nausea, vomiting, yellowing of skin or eyes (jaundice), dark urine, abdominal pain, joint pain and clay-colored stools. However, some infected persons have **NO symptoms**.

There are three common types of hepatitis, A, B, and C. Hepatitis B virus can be spread by sexual contact through exposure to infected body fluids or blood. Examples include exposures to needles or lancets, receiving tattoos or body-piercings from poorly sterilized equipment, and sharing items such as razors or toothbrushes. It also can be spread from infected mothers to their newborns during the birth process and to unvaccinated household members.

There is an effective vaccine to prevent Hepatitis B infection. If there are any unvaccinated or incompletely vaccinated persons living in your household, we strongly recommended that they report to the local health department or their primary care physician for testing and vaccination.

If I can	be of help	m answering	questions	for you, please	call my	office at	·
Sincere	ly,						

Your Name/ Title

Public Health Authority Letter



Your Health Department Address: Your Name: Your Phone Number and Your Fax Number: Your Email:

Today's Date

To Whom It May Concern:

This letter is to address any questions or concerns that may arise regarding public health investigation and surveillance activities and rules as they relate to patient privacy protection. The Communicable and Environmental Diseases and Emergency Preparedness section (CEDEP) of the Tennessee Department of Health (TDH) conducts surveillance for a number of communicable diseases and other public health threats in its capacity as a public health authority as defined by the Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule) [45 CFR §164.501].

The authority to conduct surveillance, which may include patient or provider interviews, and examination of isolates and/or medical recordreviews, comes from the Communicable Diseases Rules of the Tennessee Code Annotated. Under the law the Commissioner of Health delegates authority to the Chief Medical Officer to "make sanitary inspections and inquiries respecting the causes of diseases..." (TCA 68-1-104[2]). The Rules state that the health officer or designee shall "establish a complete epidemiological investigation to include (but not limited to) review of appropriate medical and laboratory records, interviews of affected persons and controls, and record the findings on a communicable disease field report." "Medical records shall be made available when requested, for inspection and copying of, by a duly authorized representative of the Department while in the course of investigating a reportable disease under these regulations." (1200-14-1-15).

Pursuant to 45 CFR §164.512(b) of the Privacy Rule, covered entities such as hospitals may disclose, without individual authorization, protected health information to public health authorities "...authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions...".

Thank you for your continued cooperation in these surveillance efforts, and contributions to our shared mission of protecting the health of our population. Please let me know if you have any questions.

Sincerely,

Your Name / Title

VA Medical Record Request



COMMUNICABLE AND ENVIRONMENTAL DISEASES

AND EMERGENCY PREPAREDNESS

4º FLOOR, ANDREW JOHNSON TOWER

710 JAMES ROBERTSON PARKWAY
NASHVILLE, TENNESSEE 37243

Date: To: Veteran's Administration at: Attention: Release of Information Office
Re: (Veteran's Full Name): Date of Birth: (mm/dd/yyy): Social Security Number (if known):
The Tennessee Department of Health is conducting a public health disease investigation of the above named patient, under our authority to "make sanitary inspections and inquiries respecting the causes of diseases" (TCA, 68-1: 1,04[2]). The Rules state that the health officer or designee shall "establish a complete epidemiological investigation to include (but not limited to) review of appropriate medical and laboratory records, [and] interviews of affected persons and controls." "Medical records shall be made available when requested for inspection and copying of, by a duly authorized representative of the Department while in the course of investigating a reportable disease under these regulations." (1200-14-1-15). Pursuant to 45 CFR §164.512(b) of the Privacy Rule, covered entities such as hospitals may disclose, without individual authorization, protected health information to public health authorities " authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions". I am requesting this information under the authority delegated to me by the Tennessee Department of Health as outlined in the attached letter. De-identified information will not suffice for this purpose. Specific information requested (types of records):
Applicable dates: (mm/dd/yyyy, through mm/dd/yyyy): Please send these records to me at:
Thank you for your cooperation.
Sincerely,
(Name, position, contact information)



JOHN J. CREYZCHNOL MO, MPH

BILL FASLAM

March 8, 2016



Re: Release of VA records for TDU investigations of notifiable diseases

ear

Pursuant to the duties of the Tennessee Department of Health required by the Tennessee Code Annotated 68-1-104[2], to investigate reportable diseases, I specifically authorize and designate any TDH employee actively involved in the investigation of these diseases or conditions to request and obtain records in the custody of the Department of Veterans Affairs pursuant to 5 U.S.C. 552(b)(7).

This authorization extends to any TDH medical care provider, discuse investigator, epidemialogist, or staff performing their detics as defined by the Tennessee Code Annotated 68-1-104[2], and includes patient files, records, reports and demographic information in the possession of the Department of Veterars Affairs.

A photocopy of this designation may accompany any such written request for records as necessitated by 5 U.S.C. 552(b)(7). It is our expectation that requests for information will be responded to expeditionally to aid in urgent public health investigations, and prevent unnecessary morbidity and evortality.

Sincerely.

John J. Dreyzehner, MD, MPH, PACOEM

Commissioner

JJD/TJ/als

50 Floor, Andrew Johnson Tower 710 James Robertson Parkway * Nashville, FN 3*243 (615) 741-3111 * <u>www.ba.gov/health</u>

PH-1600 Form

rections for Providers: All of the information on this form is required to report, if available.		Disease/Event:		Date of Report://
The clinical information may be provided on this form, or the relevant.	Report	Reporter Name:		Phone:
patient health records may be attached. - Please attach the associated laboratory report to this form. If unavailable,	ider & Re	Lab Report: ☐ Attached ☐ Not Tested ☐ Report Unavailable		
Public Health will follow-up for the report.		Provider Name:		
- Please provide the county of the provider facility to aid in public health	Po	Phone:		Fax:
jurisdiction assignment. • If Date of Birth is unavailable, please report the age in years. If the patient		Facility: County:		
is under one year of age, please mark the box for months. If the patient is		Patient Name:		
under one month of age, please list 0 and mark the box for months. - Patient address is used to assign public health jurisdiction for the		Date of Birth:/		Race:
investigation. If unavailable, <u>Public Health will follow-up for information.</u>	멸.	*Age: D M	Ionths	☐ American Indian/ Alaskan ☐ Asian
 "Hepatitis symptoms include: fever, malaise, vomiting, fatigue, anorexia, diarrhea, abdominal pain, jaundice, headache, nausea. Reportable tick-borne diseases include: Ehrlichiosis/Anaplasmosis, Lyme Disease, Spotted Fever Rickettsiosis 	Demographics	Gender: ☐ Male ☐ Female ☐ Unknown	Ethnicity: Hispanic Not Hispanic Unknown	☐ Black/ African American ☐ Hawaiian/ Pacific Islander ☐ White ☐ Unknown
 For Tuberculosis Infection, please include the mm of induration of the skin test in the comments. 	E.	Street Address:		
	Patie	City: State:		
rections for Laboratories: aboratories should report to public health via electronic laboratory		County:		Zip Code:
eporting or a printed laboratory report.		Phone:		-
complete this form only if the patient demographics or provider contact information are unavailable in the laboratory report.		Illness Onset Date:	//	
The clinical information section is not required for laboratory		Hospitalized? □ Yes □ No □ Unknown Hospital Name:		
eporting. The required data elements for laboratory reporting are below:	5	Admission Date:		Discharge Date://_
Patient demographics (shown on the right, including address)	nformation	Hepatitis symptom:	57H. 🗆	Yes No Unknown
Ordering provider and facility: name, phone number, address Performing laboratory name, phone number, and address	횰	Fever?†tick-borne di	seases only	Yes
Reporting facility name, phone number, address	<u></u>	Pregnant? ☐ Yes ☐	No □ Unknown	Died?□Yes □No □Unknown
- Date of the laboratory report	Clinical	Comments:		
- Test performed - Accession number				
- Specimen and collection date				
 Result, interpretation (quantitative <u>and</u> qualitative), and reference range 				

PH-1600 REDCap Reporting Link: https://redcap.health.tn.gov/

Accurint Record Search Request Form

Staff Name/Title:	Phone (xxx-xxx-xxx):	Email Address:	Office Address:
			*
Prism Profile ID # (or Patient Name, DOB, etc.) ¹ :	Patient Type:	Specific locating information needed ² :	Reason for request/ brief description of attempts to contact patient ³ :
	☐ 900 case/ contact ☐ Early 700 case/ contact ☐ Pregnant case ☐ Pregnant contact ☐ Congenital case ☐ Congenital contact		
Supervisor:	Supervisor Phone:	Supervisor Email:	Notes:

Please send any Accurint requests to Jennifer Black securely at Jennifer.Black@tn.gov

Appendix C:
Adding Providers/Organizations and NBS and Lab Translator

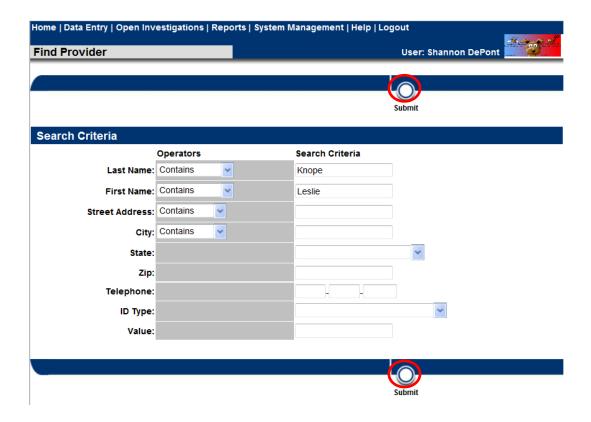
Data Entry: Adding Providers

Note a Provider within NBS is both a Physician (Medical Provider) and an Investigator (i.e. NBS Investigator). Please enter them as follows:

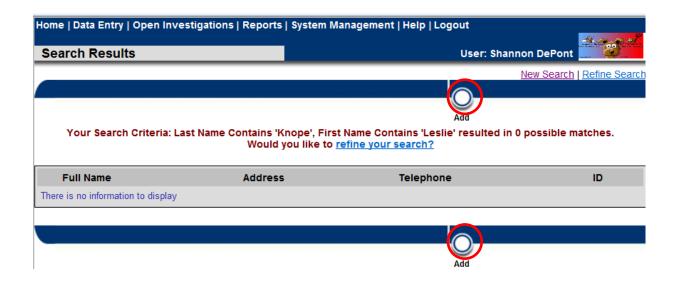
1. From NBS Home page choose Data Entry then Provider:



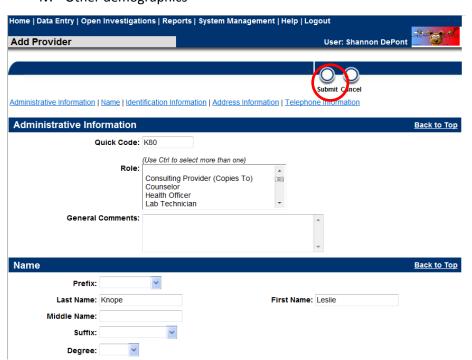
2. Under Search Criteria search for the Provider using their name followed by Submit button:



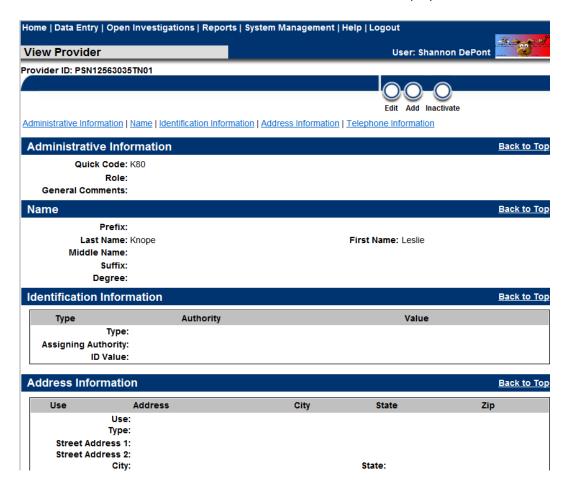
3. The search will return no results and the option to Add the Provider:



- 4. Fill in corresponding information then Submit
 - a. NBS Investigator
 - i. Quick Code
 - ii. First and Last name
 - b. Physician (Medical Professional):
 - i. First and Last name
 - ii. Address
 - iii. Phone number
 - iv. Other demographics



5. Once new Provider has been submitted the below screen will display:



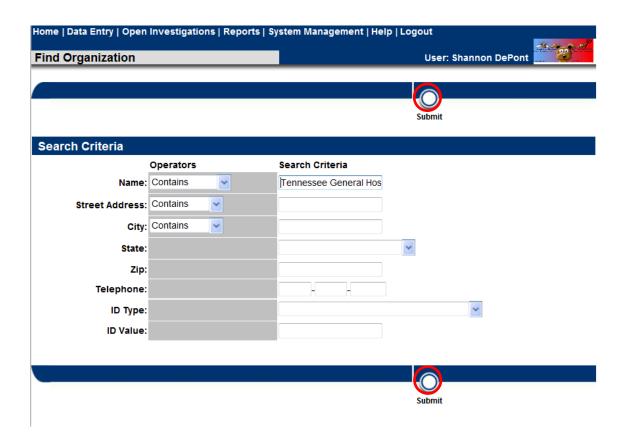
Data Entry: Adding Organizations

Note an Organization within NBS is both Laboratory and a Medical Facility. Please enter them as follows:

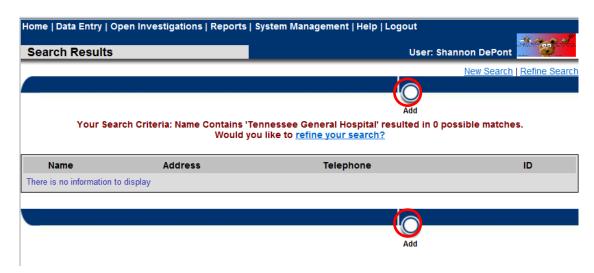
1. From NBS Home page choose Data Entry then Organization:



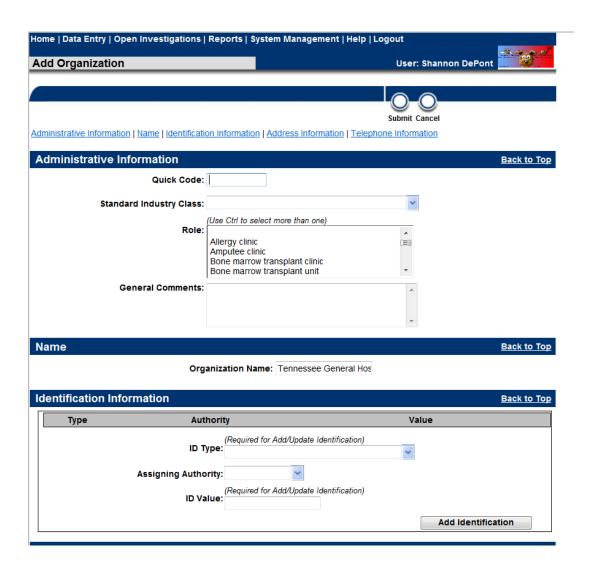
2. Under Search Criteria search for the Organization using the facilities name or address followed by Submit button:



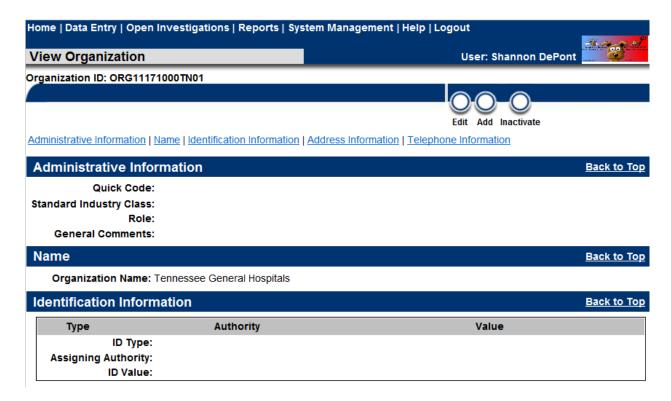
3. The search will return no results and the option to Add the Organization:



- 4. Fill in corresponding information then Submit
 - a. Laboratory
 - i. Quick Code
 - ii. Lab's name
 - iii. Address
 - iv. Phone number
 - b. Medical Facility:
 - i. Medical Facility's name
 - ii. Address
 - iii. Phone number



5. Once new Organization has been submitted the below screen will display:



Data Entry: Lab Translator for Entering a Laboratory Report

On the sheet	Ordered Test	Resulted Test	Where	How
Нер С				
HCV RNA Quant	Hepatitis C virus, RNA	Hepatitis C virus, RNA	Numeric Result	Write in number
*HCV RNA Log	Hepatitis C virus, RNA	Hepatitis C virus, RNA	Text Result	Write 'HCV RNA Log'
HCV RNA, PCR, QN	Hepatitis C virus, RNA	Hepatitis C virus, RNA	Numeric Result	Write in number
HCV PCR	Hepatitis C virus, RNA	Hepatitis C virus, RNA	Coded Result	Drop down 'Detected'
HCV RNA Viral Load	Hepatitis C virus, RNA	Hepatitis C virus, RNA	Numeric Result	Write in number
HCV RNA, Qualitative	Hepatitis C virus, RNA	Hepatitis C virus, RNA	Coded Result	Drop down 'Positive', 'Reactive' or 'Negative'
HCV NAT (Qualitative)	Hepatitis C virus, RNA	Hepatitis C virus, RNA	Coded Result	Drop down 'Positive', 'Reactive' or 'Negative'
HCV NAT (Quantitative)	Hepatitis C virus, RNA	Hepatitis C virus, RNA	Numeric Result	Write in number
HCV Genotype, LiPA	Hepatitis C Virus (HCV), Genotyping	Hepatitis C Virus (HCV), Genotyping	Text Result	Write '1b', '1a', '3a',
Hep C Ab > 11.0	Hepatitis C Virus (HCV) Antibody	Hepatitis C virus (HCV), Antibody	Coded Result	Drop down 'Positive' or 'Reactive'
ANTI-HCV (HEPATITIS C) > 11.0	Hepatitis C Virus (HCV) Antibody	Hepatitis C virus (HCV), Antibody	Coded Result	Drop down 'Positive' or 'Reactive'
Hepatitis C Antibody (HCV) IgG	Hepatitis C Virus (HCV) Antibody	Hepatitis C virus (HCV), Antibody	Coded Result	Drop down 'Positive' or 'Reactive'
HCV EIA	Hepatitis C Virus (HCV) Antibody	Hepatitis C Virus (HCV), Antibody	Coded Result	Drop down 'Positive' or 'Reactive'
ALT (Liver Test)	Alanine Aminotransferase (ALT/GPT/SGPT)	Alanine Aminotransferase (ALT/GPT/SGPT)	Numeric Result	Write in number
AST (Liver Test)	Aspartate Aminotransferase (AST, SGOT, GOT)	Aspartate Aminotransferase (AST/ SGOT/ GOT)	Numeric Result	Write in number
HCV Ag	HCV Ag	HCV Ag	Coded Result	Drop down 'Positive', 'Reactive' or 'Negative'

On the sheet	Ordered Test	Resulted Test	Where	How	
Нер В					
Hepatitis B	Hepatitis B	Hepatitis B virus		Write in 'Confirmed' or	
Surface Antigen	Surface Antigen	Surface Antigen	Text	drop down 'Positive' or	
Confirmation	(HBsAg)	(HBsAg)	Result/Coded	'Reactive'	
	Hepatitis B	Hepatitis B virus		Write in 'Confirmed' or	
	Surface Antigen	Surface Antigen	Text	drop down 'Positive' or	
HBsAg	(HBsAg)	(HBsAg)	Result/Coded	'Reactive'	
Hepatitis B					
Suface	Hepatitis B	Hepatitis B virus		Write in 'Confirmed' or	
Antibody,	Surface Antibody	Surface Antibody	Text	drop down 'Positive' or	
Qualitative	(HBSAb)	(HBSAb)	Result/Coded	'Reactive'	
HBV NAT	Hepatitis B Virus,	Hepatitis B Virus,		Drop down 'Positive',	
(Qualitative)	DNA	DNA	Coded Result	'Reactive' or 'Negative'	
HBV NAT	Hepatitis B Virus,	Hepatitis B Virus,			
(Quantitive)	DNA	DNA	Numeric Result	Write in number	
Hepatitis B					
Virus DNA PCR				Drop down 'Detected'	
(Ultraquant)	Hepatitis B Virus,	Hepatitis B Virus,		(Ultraquant is still a coded	
Interp.	DNA	DNA	Coded Result	qualitive-type result)	
-				Drop down 'Detected'	
HBV Qnt by	Hepatitis B Virus,	Hepatitis B Virus,		(Ultraquant is still a coded	
PCR (IU/mL)	DNA	DNA	Coded Result	qualitive-type result)	
Hepatitis B	Hepatitis B Virus,	Hepatitis B Virus,			
DNA Log	DNA	DNA	Text Result	Write in 'Hep B DNA log'	
Hepatitis B	Hepatitis B Virus,	Hepatitis B Virus,			
DNA Quant	DNA	DNA	Numeric Result	Write in number	
**Hepatitis B	Hepatitis B Virus,	Hepatitis B Virus,			
DNA Qual	DNA	DNA	Coded Result	Drop down 'Positive'	
Hepatitis Be					
Antibody	Shred	Shred	N/A	N/A	
Hepatitis Be	Hepatitis Be virus	Hepatitis B virus e			
Antigen	Antigen (HBeAg)	antigen	Coded Result	Drop down 'Reactive'	
Hepatitis B	Hepatitis B virus	HEPATITIS B VIRUS		Drop down 'Positive' or	
Core Ab	core antibody	CORE AB.IGM	Coded Result	'Reactive'	
HBV DNA Viral	Hepatitis B Virus,	Hepatitis B Virus,			
Load	DNA	DNA	Numeric Result	Write in number	
	Alanine				
	Aminotransferas	Alanine			
	е	Aminotransferase			
ALT (Liver Test)	(ALT/GPT/SGPT)	(ALT/GPT/SGPT)	Numeric Result	Write in number	
,	Aspartate				
	Aminotransferas	Aspartate			
	e (AST, SGOT,	Aminotransferase			
AST (Liver Test)	GOT)	(AST/ SGOT/ GOT)	Numeric Result	Write in number	
,	Hepatitis B virus	HEPATITIS B VIRUS		Drop down 'Positive' or	
IgM HBcAb	core antibody	CORE AB.IGM	Coded Result	'Reactive'	

Notes		
* Only enter HCV RNA Log if HCV RNA Quant was not	Only enter HCV RNA Log if HCV RNA Quant was not	
provided with same collection date.		
*When Q.A.ing HBV, DNA we would rather have a quant		
(number) than a qual (pos/confirmed/detected) result.		
You can skip entering a qual as long as a quant is entered		
(dates must be the same).		
*Nucleic Acid Test (NAT)/Nucleic Acid Amplification Test		
(NAAT): A molecular technique that tests for the presence		
of a virus or bacterium by testing for the presence of viral		
DNA (for HBV)/viral RNA (for HCV). *NAT testing can		
be quantitative or qualitative. For HBV: NAT encompasses		
PCR and DNA tests. For HCV: NAT encompasses PCR, RNA,		
and genotype tests*		

For an electronic version of the Lab Translator, please visit SharePoint or email Shannon De Pont at shannon.depont@tn.gov

Appendix D: Viral Hepatitis Case Notifications Process The procedures for creating a notification are changing in 2017 (see below for a detailed process). Central Office will now have final notification approval for cases that are sent to the CDC. The region will create a notification when the investigation is completed and ready for review at Central Office. Central Office will review the investigation, and if complete, will approve the notification for the case to be sent to CDC.

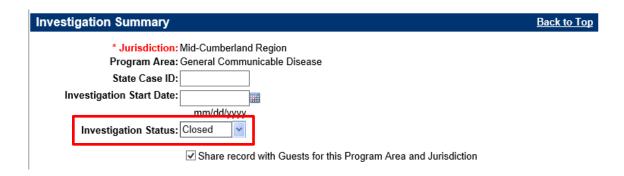
Do <u>not</u> create notifications on the following:

- Patients who are not residents of Tennessee
- Investigations with a case status of Unknown or Not a Case

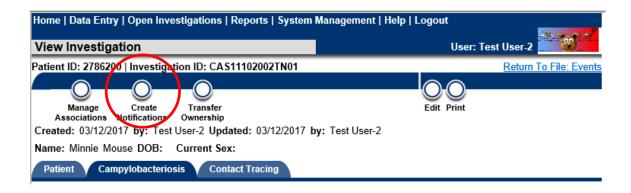
Note: If notifications are created on the above, they will be rejected and fall out of the rejection queue after 14 days.

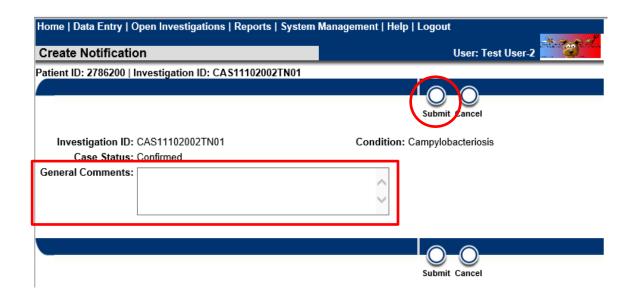
Case Notification Process in NBS

1. Complete the investigation and change the investigation status to Closed.

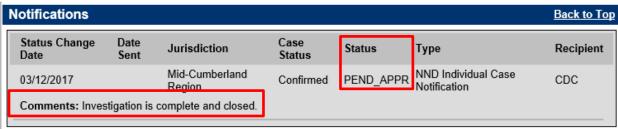


2. Click on Create Notification. In the Comments box, add any additional details for the receiving Central Office program. Click Submit to send the notification. Note, if you create the Notification before you are ready for Central Office review, leave the investigation Open.

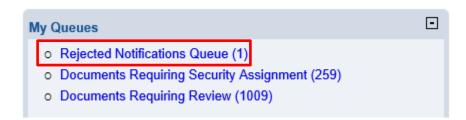


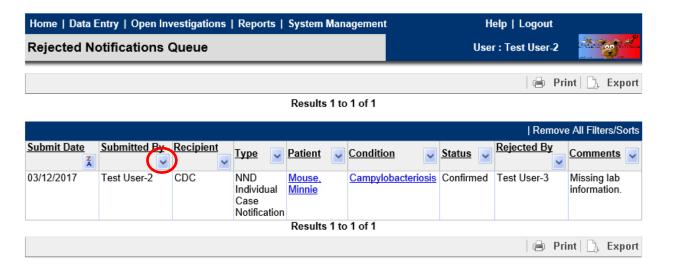


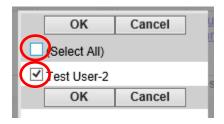
3. The notification status will now show as Pending Approval (PEND_APPR) until the Central Office program has reviewed the investigation. Note, any comments entered when the notification was created will show.



- 4. If the notification is approved, the notification status will change to Approved. When the notification is in the process of being sent to CDC, the status will be Batch Processing. Once sent to CDC, the notification status will change to Completed, if there is no error.
- 5. If the notification is rejected, the investigation will be listed in the Rejected Notifications Queue. Check the queue regularly, filtering on your name as Submitted By, to identify any investigations to review. To filter, click on the down arrow below Submitted By. Uncheck Select All, and then check only your name. Click OK.



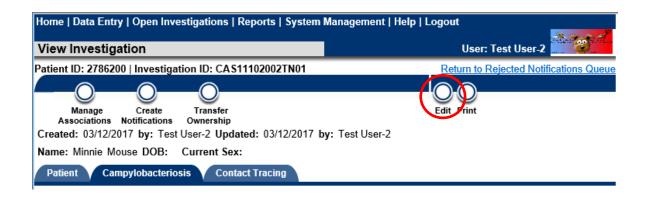




6. Note, the Comments field shows what needs revised for the investigation. Click on the hyperlink under Condition to go directly to the investigation to review. If you click on the patient name, you will be directed to the Summary tab for that patient, rather than the investigation. Clicking on the investigation will allow you to return to this list you just filtered.



7. Click Edit to make changes to the investigation. Click Submit when complete.





8. Send the notification to the Central Office again by clicking on Create Notification. Enter any comments in the comments box, and click Submit. The investigation will be returned to the Central Office to review again. The notification status will again show as Pending Approval. Any comments entered when the notification is resubmitted will show. All steps of the process will be logged in the Notification section of the investigation. Note, this section may be on different tabs for different conditions.





ю	tifications						Back to		
	Status Change Date	Date Sent	Jurisdiction	Case Status	Status	Туре	Recipier		
=	03/12/2017		Mid-Cumberland Region	Confirmed	PEND_APPR	NND Individual Case Notification	CDC		
	Comments: Lab data have been entered. Investigation is updated.								
	03/12/2017		Mid-Cumberland Region	Confirmed	REJECTED	NND Individual Case Notification	CDC		
	Comments: Missing lab information.								
	03/12/2017		Mid-Cumberland Region	Confirmed	PEND_APPR	NND Individual Case Notification	CDC		
	Comments: Investigation is complete and closed.								

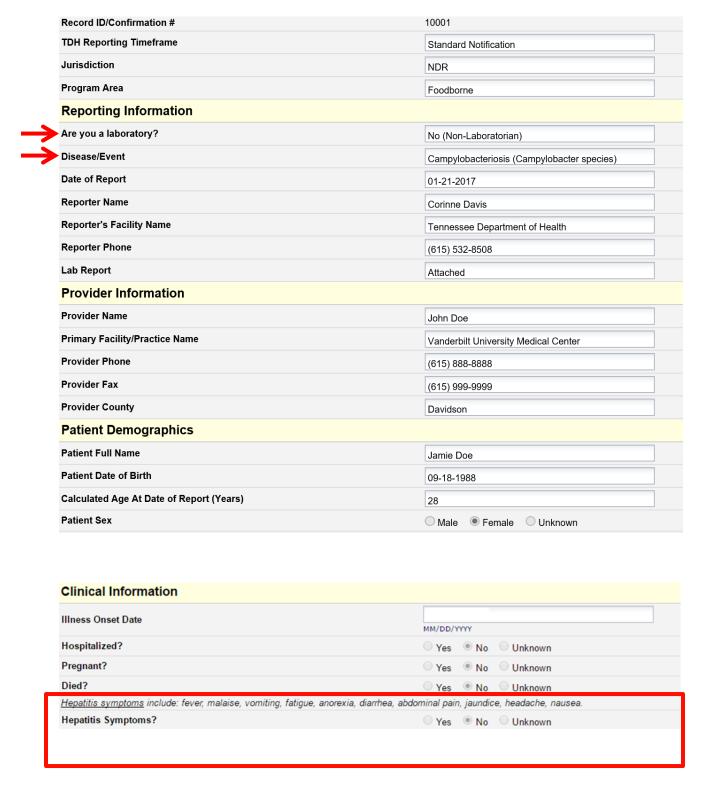
9. Click on Return to Rejected Notifications Queue to review additional investigations. The investigation you just reviewed will be removed from this queue and moved to the Approval Queue for the Central Office.





Appendix E: PH-1600 Reporting in REDCap Procedure

The person reporting the PH-1600 form via REDCap can first indicate if they are a provider or a laboratory. Additionally, they can indicate which condition they are reporting (acute HBV, chronic HBV, acute HCV, or chronic HCV) as well as if symptoms were present. Of note, the hepatitis symptoms box is not a required field and can be left blank.



The Surveillance Systems and Informatics Program prints any PH-1600 they receive for any of our conditions and give them to Central Office staff for data entry (HCV) or send it directly to the region (HBV), as with any paper laboratory report received.

For those received at Central Office, the protocol will be as follows for any HCV PH-1600 received via REDCap:

- o If symptoms are checked 'yes', we will look the patient up in NBS to determine if they have already had an acute investigation.
 - If there is an existing NBS record indicating an already regionally addressed acute field investigation, we will enter the laboratory reports and update the case status or create the chronic HCV investigation, if necessary.
 - If there is not an existing NBS record, we will email the region the REDCap Number for the region to field investigate.
- If symptoms are checked 'no', 'unknown', or left blank, we will review the attached REDCap records (if applicable) and if suggestive of acute, we will email the REDCap Number to the region to field investigate.
 - If not suggestive of acute, we will treat as chronic HCV and enter the laboratory reports and create the investigation centrally.